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CONTRACTING ORGANIZATION: Clinical Technologies Corporation
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Long-term monitoring of cardiac patients at risk for critical, life-threatening arrhythmias, with wearable electronic equipment is cumbersome, due to the difficulties in the application of the electrodes, artifacts from motion , EMI, and the lack of reliable software in recognizing abnormal rhythms. There is a need for long-term monitoring without discomfort. Benefits to the military would provide a monitoring system for battlefield casualties and for the study of subjects in simulators. This project can effectively replace current electrodes overcoming artifact and patient compliance problems. The possibility is clearly in sight for automatically alerting a rescue team to deliver its services to a victim promptly and appropriately for the condition.

Through the work in Phase I, we found the technology to accomplish long-term monitoring with a high level of compliance, with significantly reduced artifacts and with sufficient information to classify arrhythmias accurately. Phase I resulted in prototypes which have been evaluated on normal subjects with success, demonstrating the feasibility of the majority of the above objectives. We developed "smart sensors" for recording and interpreting the electrical activity of the heart noninvasively, as well as developing a harness that may be worn comfortably by a subject.

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INTRODUCTION

Long-term ambulatory monitoring is fraught with the following major problems today: interference and artifact rejection, the lack of high quality electrode contacts with the patient's skin and patient compliance. These problems are interdependent: good contacts do reduce artifacts although they do not eliminate them. The preparation of high quality skin contacts is time consuming for contemporary electrodes, and generally not easy to apply by an untrained person. It calls for thorough cleaning of the skin, firm application of the electrodes with a stable, conductive and non-irritating medium and it is not conducive for long term application. All this depends on the patient's ability and willingness to comply with complex instructions.

Our objective was to test the feasibility of the development of a "Smart Sensor" that is physically and economically sound for manufacturing, and in combination with an electronic design, it minimizes artifacts. The objective is the monitoring of arrhythmias and their accurate and rapid classification. The sensors are to be worn in a manner designed for easy compliance by the patient, and self-administered by the user. So far, we have limited this technology to electrocardiographic signals, however it is feasible to use this technology for EEG and EMG monitoring.

The principle of spatially differentiating electrodes and the method of triangulation were introduced in our Phase I proposal as our approach to arrhythmia analysis. The principles will be briefly restated here:

Planar concentric electrodes are sensitive to events which take place in their immediate vicinity while they ignore events elsewhere. When a wave front, represented by a dipole layer is moving toward the sensing site and passes these electrodes, the unipolar electrode produces the largest and broadest signal, the linear bipolar signal is smaller and better defined in time, while the concentric ring electrodes provide an even smaller but very well defined signal. The concentric ring electrodes offer the advantage of omnidirectionality, hence, they are well-suited for the determination of the moment when a wave front passes them. These properties have been studied in simulations, in tank experiments and in animals with the electrodes applied directly to dog hearts, and have also been published. In our Phase I work we also evaluated these concepts, noninvasively, on humans.

The principle of triangulation was proposed for adaptation to cardiac monitoring and to interference reduction. The general principle is that both normal depolarization patterns (NSR -- normal sinus rhythm) and abnormal but periodic patterns (VT -- ventricular tachycardias, reentry tachycardias, etc.) follow the same propagation pathways beat after beat. The moment of activation (MOA) at a concentric electrode site can be determined from the peak of the time

derivative of the signal obtained from the electrodes. The delays obtained between three or more sensing sites and the time between sequential activations of the sites provide a beat signature suitable for rhythm identification.

RESULTS OF PHASE I WORK

The objectives of Phase I have been achieved as presented below. In fact, we have progressed beyond the objectives set for Phase I.

The approach we proposed and have tested was based on sensing the moment of activation (MOI) of the heart muscle at specific sites, using tripolar concentric electrode systems. These electrodes emphasize the electrical activity in their immediate vicinity and tend to disregard interference that originates elsewhere. We considered the expected distances from the chest wall to the electrically active heart tissues and settled for a specific geometry based on both theoretical and empirical ground. The theory had been worked out by Kaufer (1992), as her MS thesis in Biomedical Engineering at the University of Miami (advisor: P. Tarjan). This thesis concluded that the optimal outer radius of the 3-ring system should be approximately equal to the distance of its center to the active muscle area. We estimated that the distance for a typical person of average build would be between 10 and 20 mm, depending on the site of application on the chest. Sensors of various dimensions were constructed and a 36 mm diameter design was selected as it provided a relatively large signal with minimal contamination from interference. The electrodes were constructed on copper-plated printed circuit boards and subsequently plated with silver-silver chloride to reduce polarization effects. The somewhat flexible but essentially flat PC boards could be applied to the subject without discomfort and without an electrode gel. Techniques were developed to cut round substrates, following the etching of the PC board.

It was determined that electrical interference was indeed a serious problem on account of the leads connecting the sensor to the amplifier and display units. The next major step in the development was the design of a battery powered amplifier of such small size that it could be mounted directly above the electrodes on the PC board. For reasons of ease of fabrication and reliability, we decided to separate the electronics from the electrode-bearing PC board and the electronic circuit is mounted with its battery on an identical size round PC board. The two boards are separated by a few millimeters. The amplifier is characterized by a very high input impedance that permits the electrodes to be applied without any conductive gel or skin preparation and can be worn for long periods. Photograph 1 shows the PC boards with the electronics and the sensing rings, laid out on the case of our lap-top computer, to indicate their size.

Testing on human skin showed that electrode polarization was still a serious problem resulting in d.c. offset voltages which drove the amplifier into saturation.

This problem was eventually eliminated without any compromise in signal quality by the insertion of a band-pass filter for the 5 Hz to 500 Hz range. This choice was based on the spectral analysis of our recorded signals.

The usual bandpass of clinical ECGs is from virtually 0 Hz to 100 Hz. The typical commercial ECG machine has a low-frequency cut-off around 0.05 Hz. This often causes long periods of signal loss due to saturation of the preamplifier. While this may be a desirable bandwidth for the assessment of baseline shifts, such as ST elevation or depression, our objectives are similar to those of bedside monitoring where the signal must be available 100 percent of the time. This is assured by the bandwidth that we selected.

The 5 Hz cut-off eliminated the offset problems without any appreciable change in the signal that is typically a biphasic or triphasic waveform with about 20 ms duration. Many of these are shown in our illustrations.

As the next step in the validation of our concepts, we aimed to determine appropriate recording sites for our sensors. We recorded from 16 sites in a 4 by 4 rectangular array from the left side of the chest. The array is subject specific. The horizontal distance between the mid-sternal line and the left nipple is divided by three to determine the size of each area. The 2-D array is marked from 00 to 33 where the first digit refers to a column and the second one to a row. There were two rows above and two rows of rectangular cells below the line running across the subject's nipple.

We collected such data from several male and female subjects and some of the results are shown in Fig. 1-5. The recordings were made with a 100 MHz Pentium laptop computer, shown in Photograph 2 along with the cable and five identical sensors attached. Each figure (1-5) represents 16 recording locations the data from each of two sites was unusable due to technical errors. Each subpanel shows two frames, the left frame shows a sequence of events which were automatically lined up for their peaks. A sequence of about 25 consecutive cycles was digitally recorded at 2000 samples per second to exceed the requirements for the desired bandwidth, according to Shannon's Sampling Theorem. The cycles were then aligned, shifted, according to their positive peaks. These were then averaged point by point for a certain number of points preceding the peak and beyond. Typically the average was determined at a total of 400 points corresponding to 200 ms. The standard deviation was also determined for each instance. The entire set of realigned cycles is shown on the left, side-by-side with the mean (μ) and the mean $\pm$ standard deviations ($\mu \pm \sigma$). The results for all 16 sites, when plotted on the same scale, reveal the best sites for recording in a triangular area. We have not yet made our choice on the basis of this preliminary data.

It should be mentioned that all of the subpanels are shown at the exact same time and amplitude scale. The time is shown in milliseconds and the range is 200 ms. The subjects were at rest, typically sitting on a chair for the recordings. The sites were recorded sequentially, rather than in parallel as we did not have a sufficient number of sensors at the beginning and the analog/digital converter could handle only two channels at the time of our recordings.

Mr. Feng, a BME graduate student, developed an algorithm for the automatic processing of such data by seeking the peak, shifting it, computing the averages and standard deviations and producing the appropriate plots. Differentiation and search for the peak of the derivative to locate the most likely MOA was not included in the algorithm. It did not appear to be necessary for our demonstration. These tasks are presently carried out on a PC but appear to be entirely suitable for a low-power microprocessor.

Figure 1 shows extremely high repeatability with very good SNR at five sites (02, 12, 13, 22 and 23) on the lower left and middle portions of the array. The best sites in Figure 2 appear at 23, 32, 31 and 22. Figure 3 yields 12, 21, 01 and 23, and so on. It seems that it is too early to determine "standard sites" for the highest quality signals and this may have to be determined for each subject until a general rule appears to emerge. Three of the "best" sites should be selected for the triangulation process as discussed below. In Photograph 3 one of the subjects shows three of the preferred sites on his chest based on amplitude, repeatability and SNR criteria.

The recording from each local site was simultaneous with a Lead II ECG. The "delays" or, rather, time shifts, between the peak of the Lead II QRS and the first extreme value (sometimes positive, sometimes negative) were determined. Some of the values were negative as the local event preceded the Lead II peak. These are shown in Figure 6.A-E for the same five subjects. The same delays were determined for the second extreme values in the local electrograms and shown in Figure 7.A-E. As these subjects were all free of ventricular arrhythmias, it was not surprising that all the delays were relatively short. This result was expected on the basis that the His-Purkinje conduction system in the healthy heart produces virtually instantaneous depolarization of the entire ventricular mass. It is one of the strengths of our approach to arrhythmia classification that signals related to the ventricular depolarization in sinus rhythm (SR) , the QRS complex in standard ECG terminology, are easy to recognize on the basis of these short delays. Ventricular arrhythmias take other routes than the His-Purkinje system and this results in slower propagation, longer shifts between extrema at different sites and the delays are characteristic of the depolarization's trajectory which is a reflection of the abnormal conduction paths.

The time between the first and second extreme values were also determined and shown in Figure 8. A-E. These intervals correspond to the inverse of the velocity of propagation. The shorter the interval, the faster the propagation. These are, naturally, all positive values and none of the delays was greater than 50 ms.

It is quite clear that not all sites produce equal amplitude and quality signals. Generally, the largest amplitudes are produced in a more or less triangular region.

We tested the variability of the signals from site to site as shown in Figures 6-8 and determined that signal averaging should be included in the processing to improve the signal to noise ratio (SNR) regarding skeletal muscle activity. This appears to be an important finding in the area of electrocardiography.

The electronic design by Chih-Cheng Lu is presented in Figure 9. The gain of the amplifier is 1000. The pass band of this circuit was from 5 Hz to 500 Hz. The low frequency cut-off was chosen to eliminate d.c. drift and the high frequency cut-off was deemed to be sufficient to include the spectrum of even the fastest transient events originating from the heart. The other notable feature is the low current drain that allows the use of on-board lithium cells which are small enough yet provide several days of service. The fabrication and testing were mostly done by students in the BME Dept. at the University of Miami.

Signal averaging is a powerful method in improving the SNR. It is commonly used in medicine to detect auditory brainstem evoked potentials by a steady series of audible clicks delivered to the subject's ear. They are also used in the detection of "late potentials" in electrocardiography where the trigger is some fiduciary point in the QRS complex to solve the problem of variations in the cycle length. We applied the same principle to our signal averaging task.

A consultant, Ms. Terri Kovacs, designed and fabricated several prototypes of wearable garments for the rapid and reliable attachment of the dry, pasteless electrodes to the subject. Photographs 4, 5 and 6 show these prototypes. Photograph 4 shows a male subject with two electrodes attached beneath the harness. The harness was designed to provide maximal freedom of movement of the subjects shoulders with minimal motion of the sensors on the chest surface. Photograph 5 shows another male subject demonstrating the freedom for arm movement while wearing the harness. Photograph 6 shows how the harness is secured over the back of the subject. The straps are adjustable, comfortable and easy to don. The material of the harness is elastic and easy to launder. However, it is inexpensive and possibly disposable. The attachment of the sensors to specific spots is based on the use of Velcro™ patches on the sensors which may or may not be disposable. This feature would be determined during Phase II of this project.

Our Phase I proposal was aimed at the following tasks with the following results:

1. Evaluate the feasibility of an active electrode system from the viewpoints of power consumption, stability, fidelity, cost, reusability and comfort.

All of these have been accomplished.

2. Assess presently available materials for pasteless ECG electrodes for l long-term monitoring.

This was solved by the electronic design.

3. Assess the artifact recognition capability of concentric electrode sets which are inherently insensitive to interference.

This has also been demonstrated by the results presented above.

4. Develop a comfortable harness or undergarment for the quick, repeatable application of surface electrodes, suitable for long term use both from the viewpoints of comfort and psychological well-being.

This has also been demonstrated and illustrated in Photographs 4-6.

The work to be described next was performed beyond the feasibility study and provides further evidence of the viability of our objective to monitor cardiac rhythm disturbances continuously.

We assumed success in obtaining measurable delays between the three activation sites. This assumption has been partly proven by our results to date. It is to be tested with arrhythmias.

Our first attempt to demonstrate delays noninvasively was based on the comparison of two channels of simultaneously collected data: one channel collected signals from a set of 3 concentric electrodes and the second channel was an approximate Lead II. Several sites were compared with the peak of the Lead II ECG from a normal subject in normal sinus rhythm (NSR). It was shown that during NSR the delays from different sites resulted in different time shifts with respect to the Lead II ECG, as was shown in Figures 6-8.

Subsequently we were able to record simultaneously from several sets of four concentric sensors on a subject who had occasional premature sinus beats. Figure 10 shows four simultaneous channels with two episodes of such prematurity. It appears that the ventricular depolarization following the first

premature atrial event is essentially the same as the normally timed ones, while the second one shows some aberration in form.

In general, although there are some variations in beat-to-beat delays in subjects with NSR, these are assumed to be the result of respiratory effects, such as displacements between the sensors and the underlying muscle regions.

The next step in the validation of the principle will take place in the cardiac electrophysiology (EP) laboratory while a patient, prone to ventricular arrhythmias, will be monitored. Arrangements have already been made with John Lister, M.D., to obtain such recordings at Broward General Medical Center. Although three trips have been made to the hospital, we have not obtained any data, although we have completed a trial run of applying the sensors to a patient who was undergoing an EP study but without any evidence of ventricular aberrations.

SUMMARY AND CONCLUSION

The majority of the issues of feasibility have already been demonstrated during Phase I. The remaining major issue of feasibility is associated with physical activity.

We have already demonstrated during Phase 1 that dry electrodes in combination with an amplifier and filter, which were integrated with the sensor system to eliminate leads, provide signals with acceptable SNRs. These signals are quite uniform and suitable for signal averaging to improve the SNR. Signal averaging is contemplated to be a useful element in the arrhythmia monitoring system to recognize changes in the morphology and the timing delays between the MOAs.

The implications of our work for the future may be summarized as follows:

1. An elastic garment, similar to our prototypes, may be used to apply a set of dry electrodes to a chest to obtain MOIs from 3 or more sites.

2. The processing of the MOI data should be sufficient to identify rhythm changes, especially ventricular tachycardias, flutter and fibrillation.

3. The signals may offer advantages in the recording of local "late potentials," and alert to ischemic episodes as the delays are expected to lengthen.

4. Signal averaging, using a running average, would provide further improvement in SNR. The signal averaging appears to require only 8 to 10 beats to achieve a desirable SNR and definition of shape, thus the

running average would provide a prompt alert signal when an arrhythmia is beginning to evolve.

If our auxiliary signal processing hardware and software function appropriately then the local maximum of the time derivative of each electrode set's output corresponds to the moment of activation (MOA) by a wave front of depolarization. The time interval between the three points of observation should provide a signature of the cardiac beat for its classification. If the MOAs are close in time then the beat is presumed to be a normal sinus event. Each ventricular activation pattern that either originates from an ectopic focus or from a reentry path would be identified by its signature: the two time delays between the three sites and the period between reactivations at each site.

The harness is intended to keep the electrodes tightly in place on the chest and force the sites to be very similar from application to application. An adjustable harness or commonly used under-shirt /undergarment for males and bra type / corset undergarments for females are envisioned on the basis of our prototypes.

The harness is intended to be easy to launder or clean, easy to apply and inexpensive to purchase. The electronics embedded in the harness will be coated with commercially available materials to prevent contact with water, or chemicals in the case of soaking, or dry cleaning, for repeatable wear.

Three, bipolarly connected, rings are planned to be used in each sensor. These will be incorporated in the harness with a connector for easy connection to the processor for monitoring. Such connectors are readily available. The development is expected to continue with the same lap-top Pentium based computer for data collection. Phase II will address problems of miniaturization and production of substantial numbers of units for trials.

The majority of the issues of feasibility have already been demonstrated during Phase I. The remaining major issue of feasibility is associated with physical activity.

POTENTIAL COMMERCIAL APPLICATIONS :

This project can effectively replace current electrodes in hospitals, ambulatory care , and emergency care monitoring. Benefits will include (a) elimination of prep time, (b) assured quality of signal, (c) subject compliance, and (d) reduced cost to purchase. It would be possible to monitor high risk cardiac patients for long term while ambulatory. The possibility is clearly in sight for automatically alerting a rescue team to deliver its services to a victim promptly and appropriately for the condition.

POTENTIAL MILITARY APPLICATIONS:

The benefits to the military would be in providing a monitoring system for battlefield casualties and for the study of the cardiac rhythms of subjects in various simulators.

PHASE II WORK PLAN

Based on the results of Phase I, the following tasks have been identified for the continuation of the development of our smart sensors.

1. Evaluate the current design on subjects with arrhythmias. The data will be used to gain further information about the most appropriate electrode sites and to be used for the development of the arrhythmia classifying algorithm. This task of the project is already arranged to start as a result of Phase I efforts.

2. Analysis of the human data for site and sequence with emphasis on refining site to site delays in activation. Performed with specific analysis software already in place as a result of Phase I efforts.

3. Re-evaluate the electronic design from the viewpoint of developing an ASIC (application specific integrated circuit) for low cost, high reliability, ease of packaging and other product design related concerns.

4. Develop fabrication techniques for integrated electrodes with the help of the manufacturing sources already selected.

5. Develop and refine algorithm and test retrospectively on earlier data.

6. Validate algorithm on subjects over periods of 24 hours. To be performed outside the lab with volunteers. Data to be correlated with 24 hour Holter monitors.

7. Refine the design of the harness, validate its use on subjects with electrodes installed in the harness. Initial design to be tested by volunteers. This continues our Phase I activities, focusing on disposability, cost reduction and manufacturability.

8. Once final design is defined, identify a source for manufacturing the harness.

9. Define and develop dedicated electronics for the purpose of performing signal averaging and the analysis of delays. The design will define suitable connections to transmission units, such as a cellular telephone

with automatic dialing when activated by an alarm. The algorithms have already been defined by Chih-Cheng Lu, and are to be further developed.

10. Develop the interpretation of the output of the device that will not require special training in electrocardiography and will be unequivocal.

11. The ultimate prototype including the electrodes, harness, signal processing and analysis unit, and link to the transmitting device will be assembled and tested on the bench, on healthy volunteers and on subjects with documented arrhythmias.

12. As a separate development task, the concept of incorporating an accelerometer in the system will be evaluated and developed for the purpose of eliminating from the input data any segments of activity which coincide with specific signal characteristics from the accelerometer. This technology will be designed to maximize the elimination of artifact from movement. This process will involve:
    a. Evaluating accelerometers for the application. (In case a suitable and inexpensive commercially available accelerometer cannot be found then we have a back-up plan for an inexpensive accelerometer based on magnetic induction. A miniature permanent magnet is suspended by a spring that also serves as an inductor in which an electromotive force is induced when the magnet undergoes one dimensional acceleration. The application does not require a calibrated accelerometer but an acceleration detector with threshold detection capability to produce a go/no go output.
    b. Collecting data from healthy volunteers involved in mild to vigorous physical activity to determine correlations between noisy segments of electrical recordings and the output from the accelerometer. The analysis should allow us to conclude the feasibility of the concept to interpolate ECG segments during specific patterns of acceleration.
    c. If fruitful, integrate this development with items 9 and 10.

13. Patent rights will be continued to be worked on with our patent attorney.

14. Continue to develop business plans for commercialization.

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Subject I WF 30 YR OLD MALE HEIGHT 6' WEIGHT 135 LB

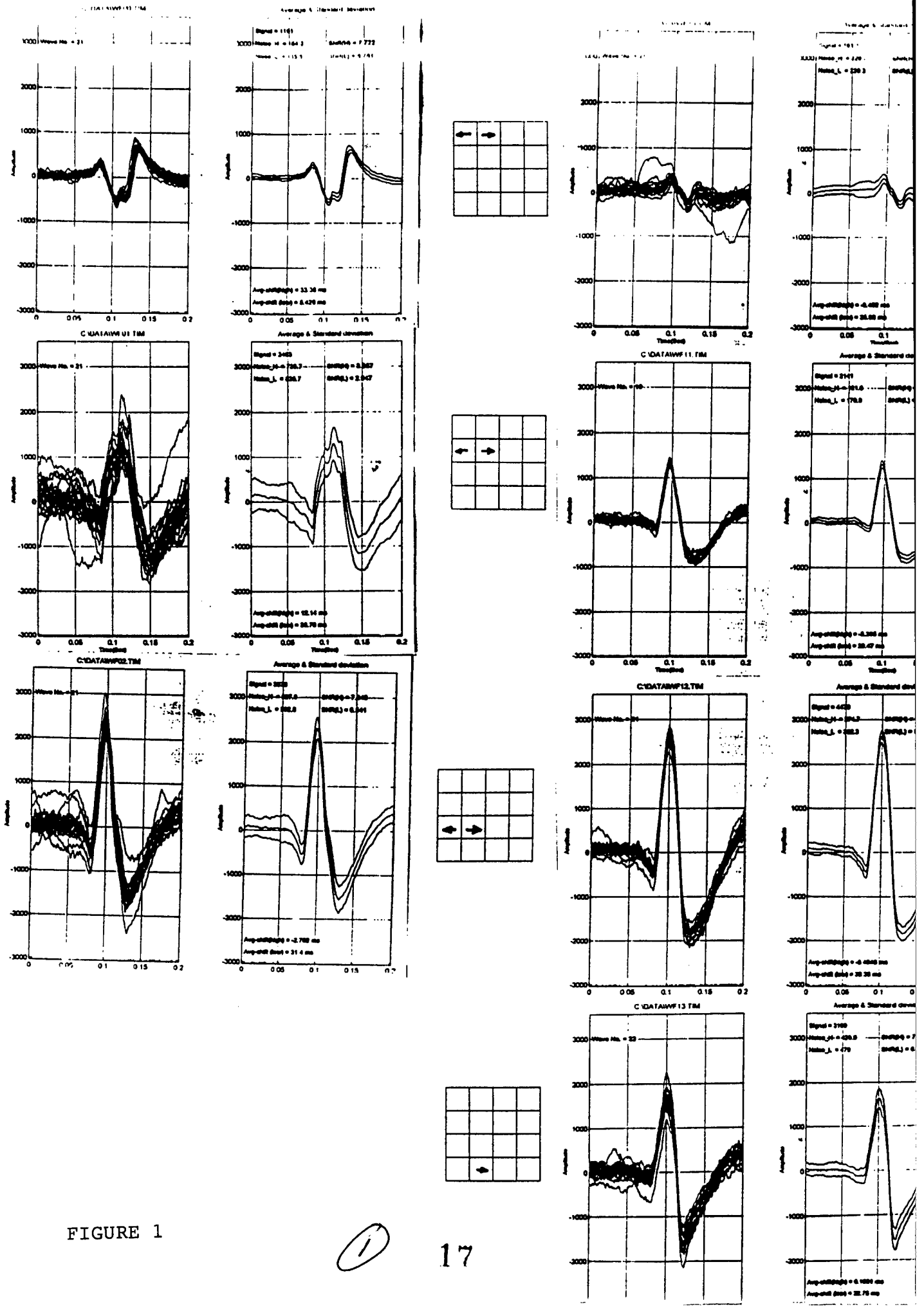
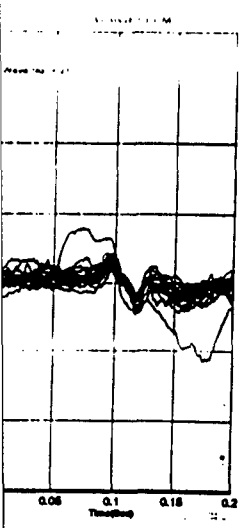
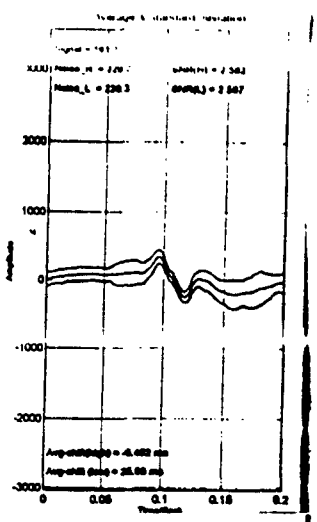
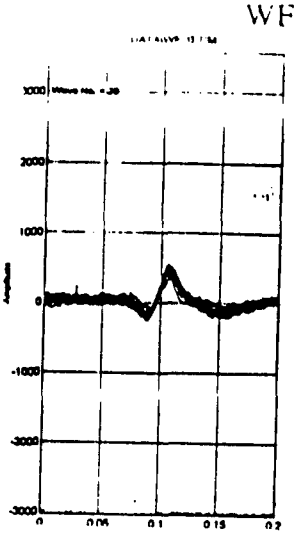
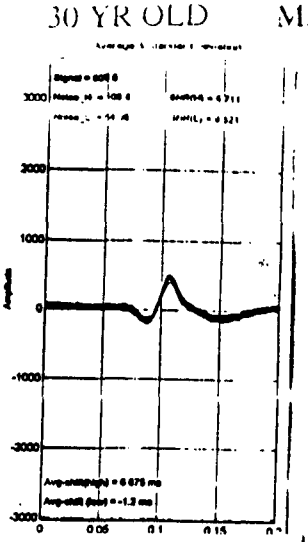
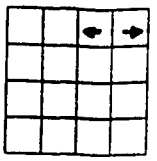
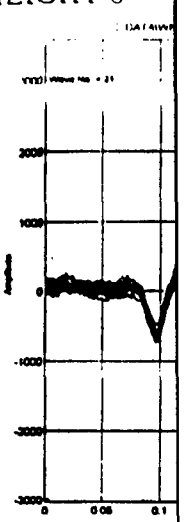
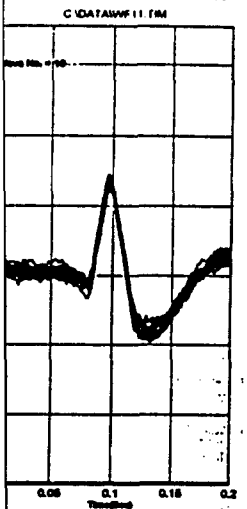
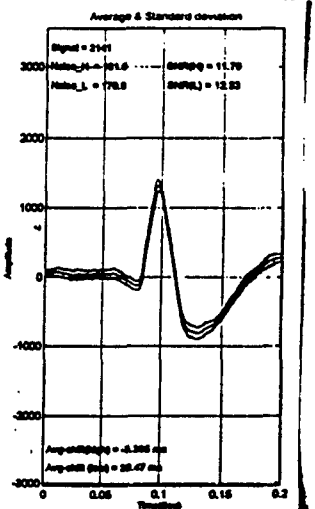
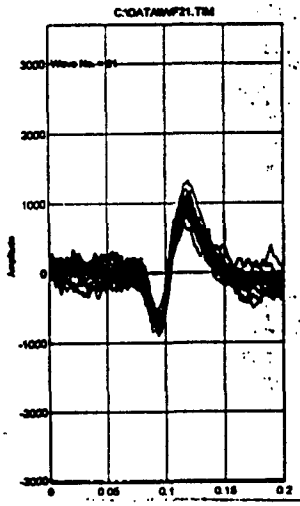


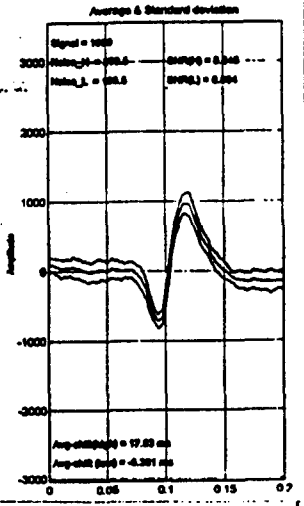
FIGURE 1

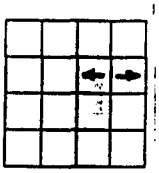
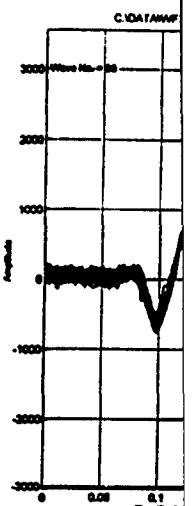
6' WEIGHT 135 LB WF 30 YR OLD MALE HEIGHT 6'

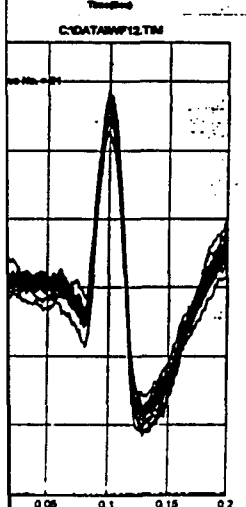








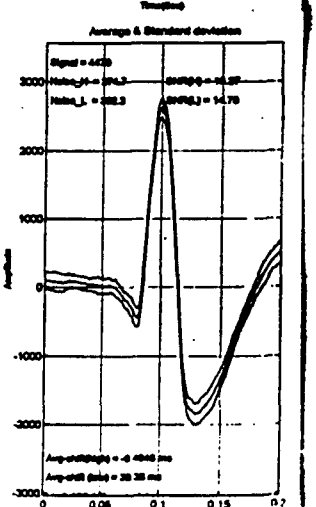


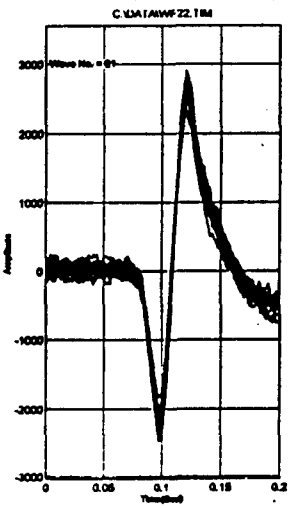


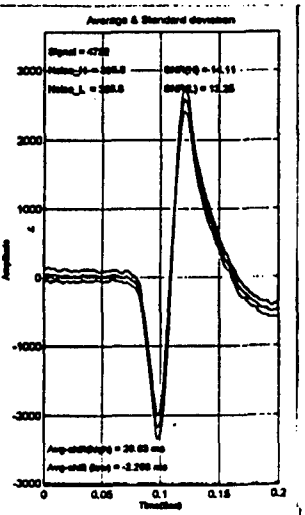


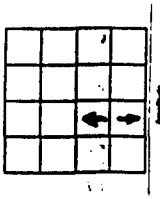
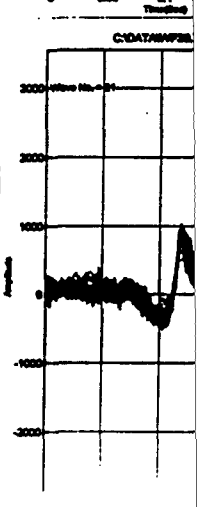



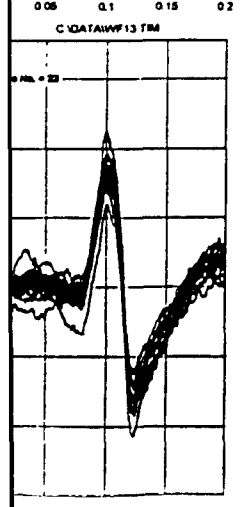


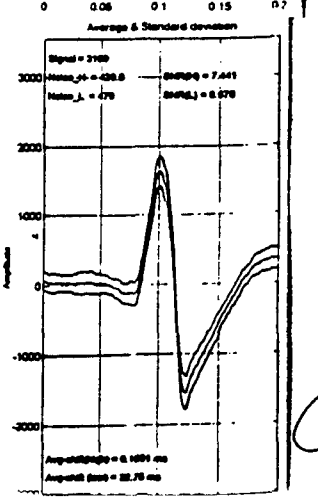


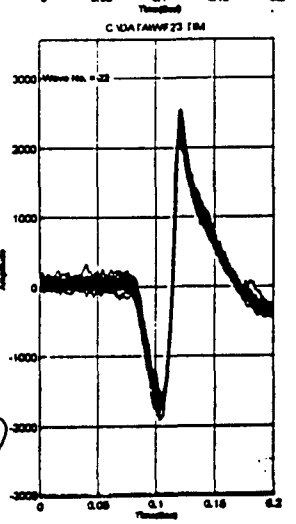


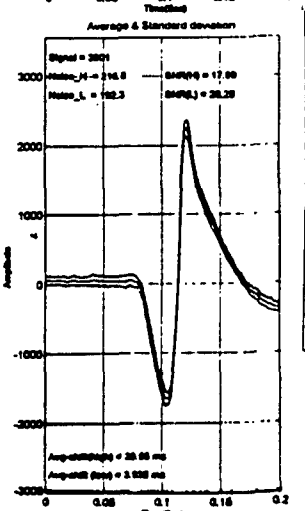


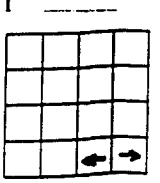





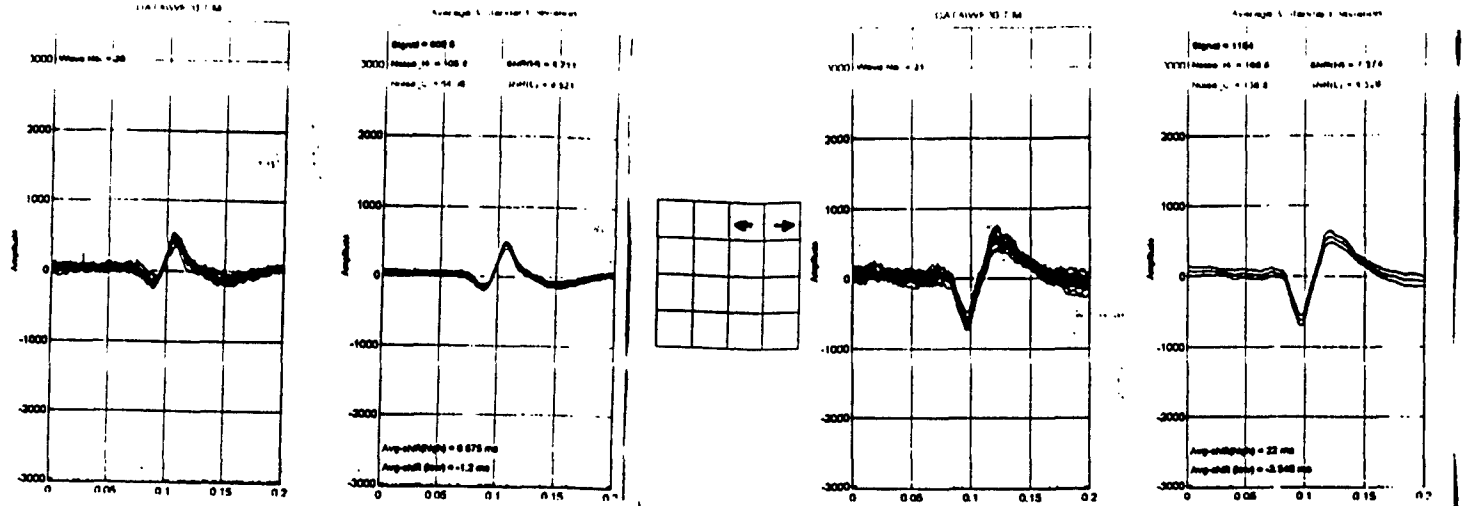


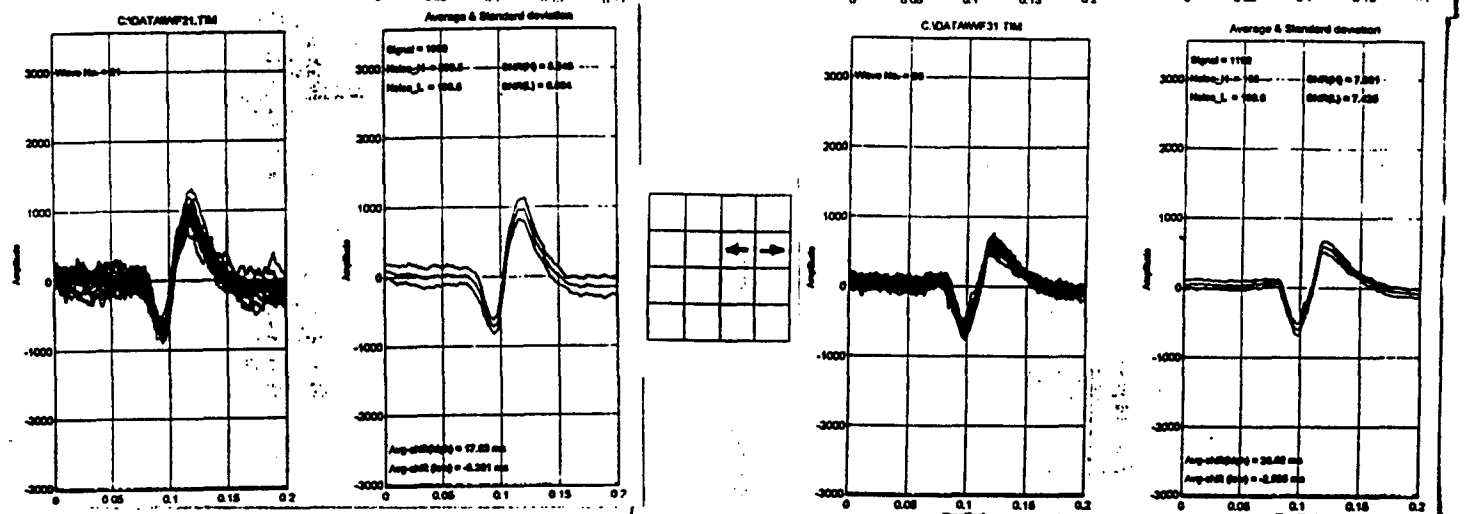


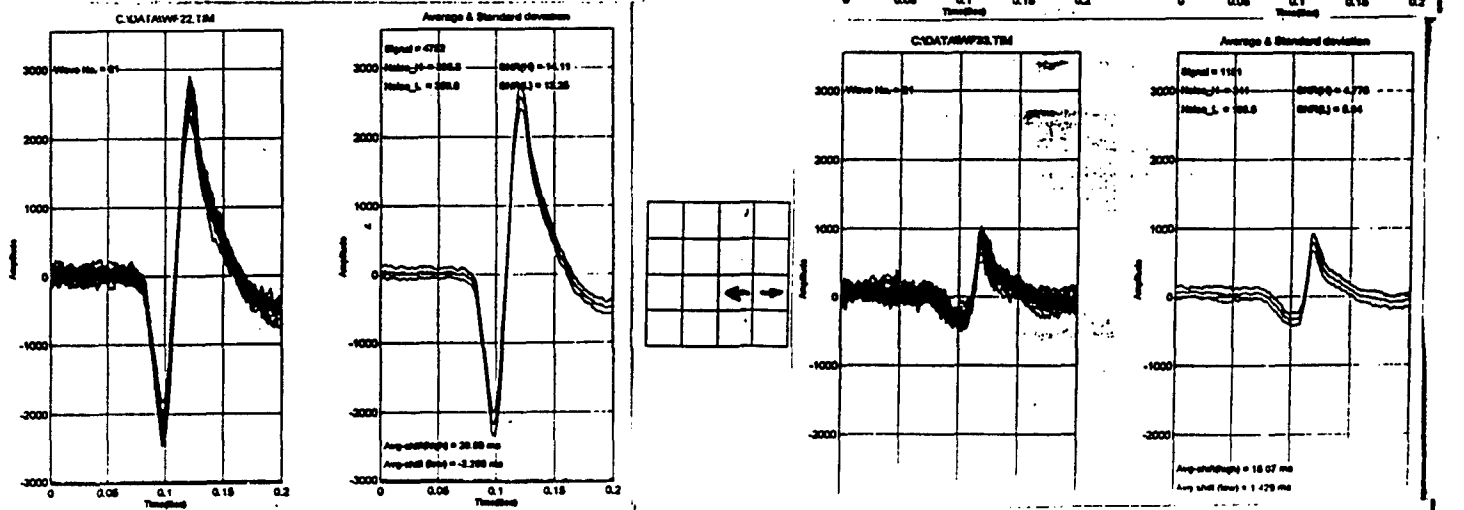


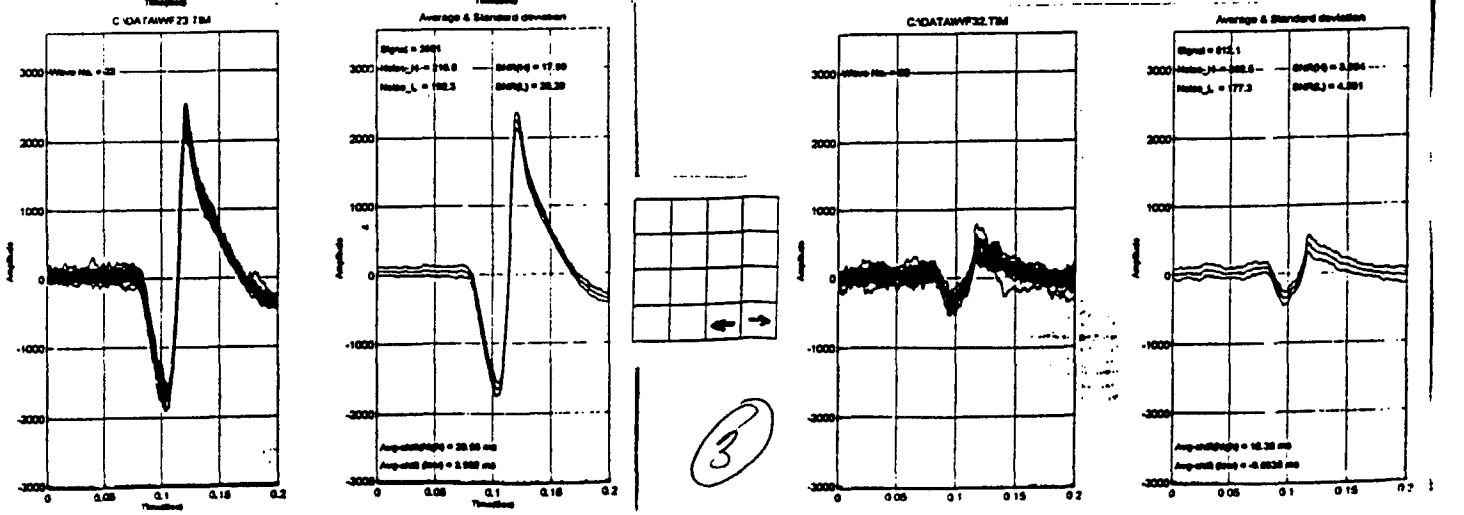


WF 30 YR OLD MALE HEIGHT 6' WEIGHT 135 LB

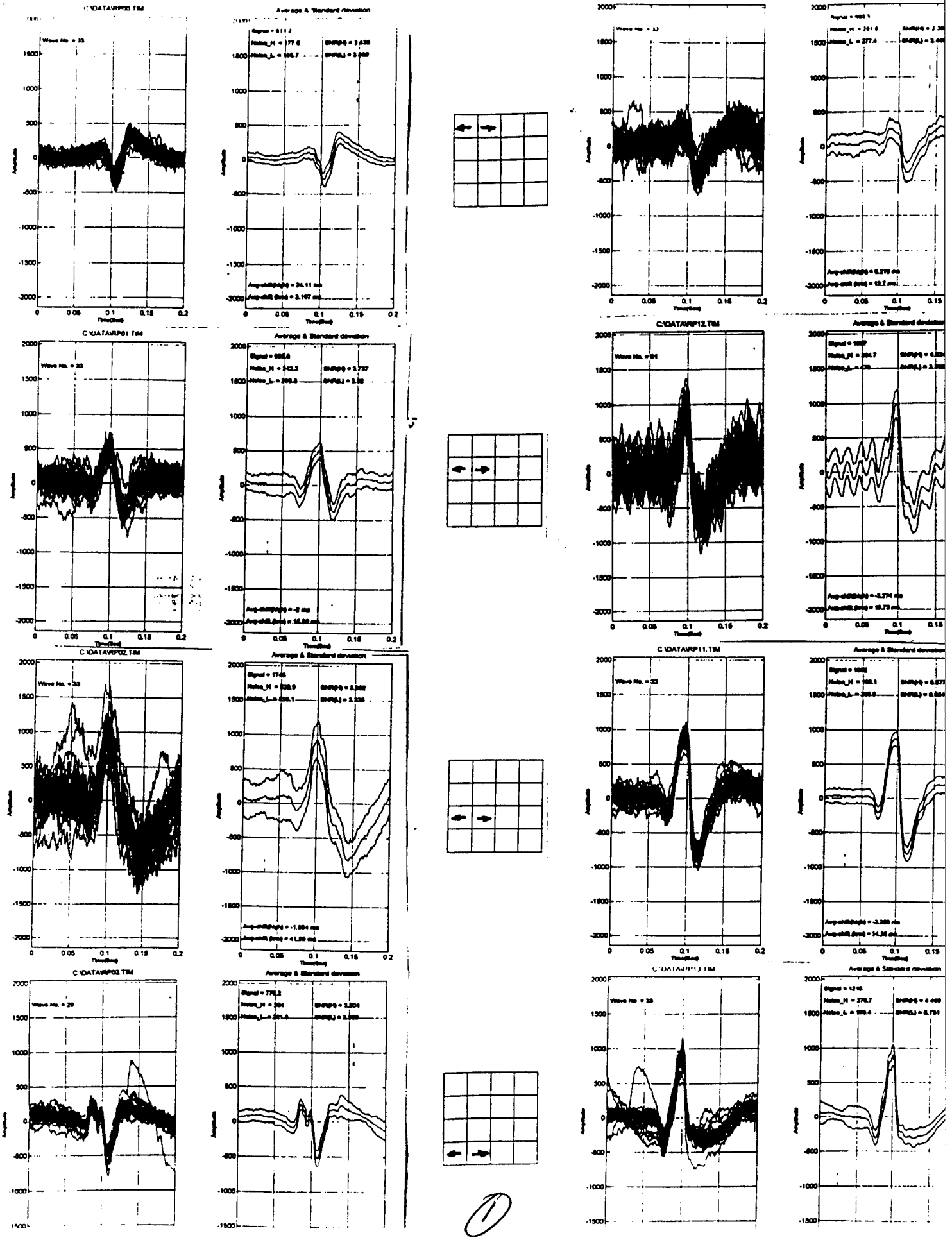




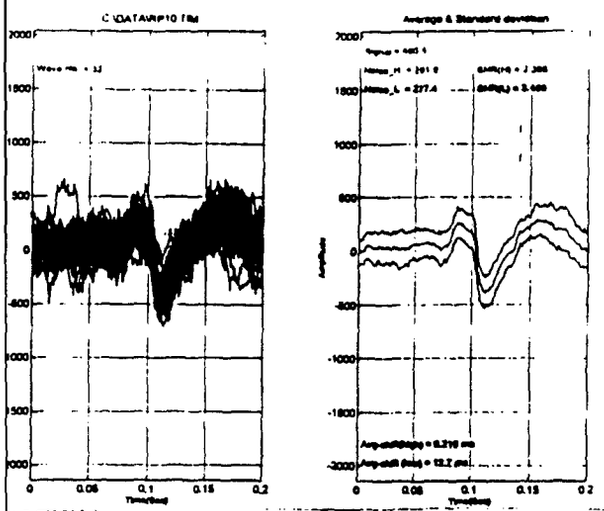


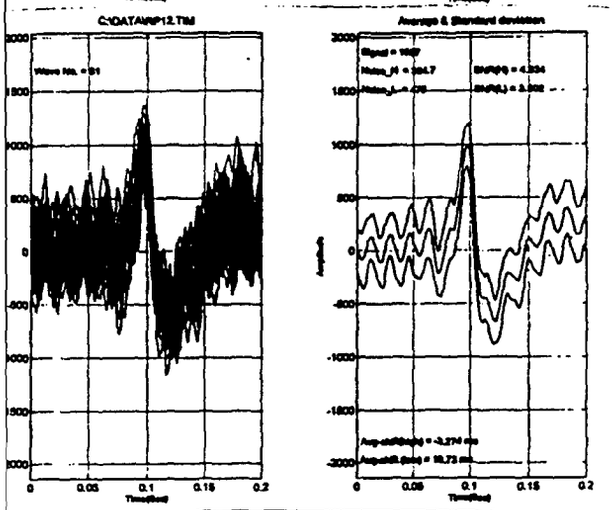


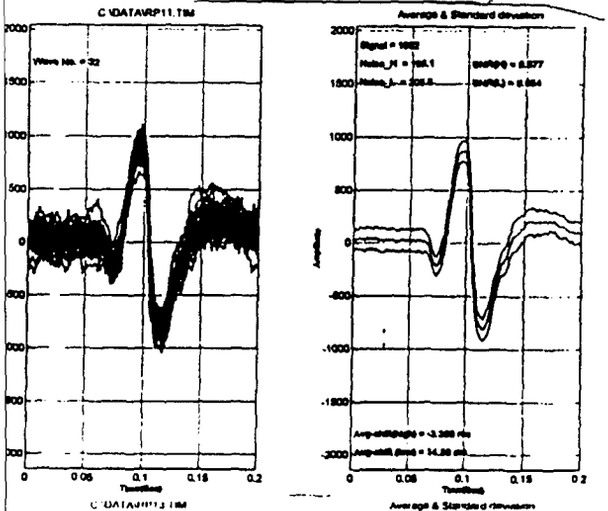
Subject II RP 36 YR OLD FEMALE HEIGHT 5'3" WEIGHT 123 LB

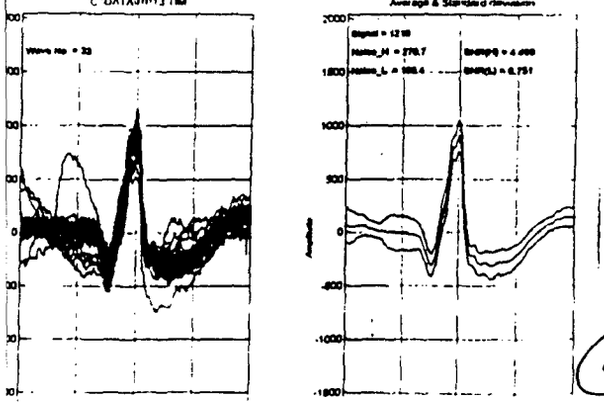


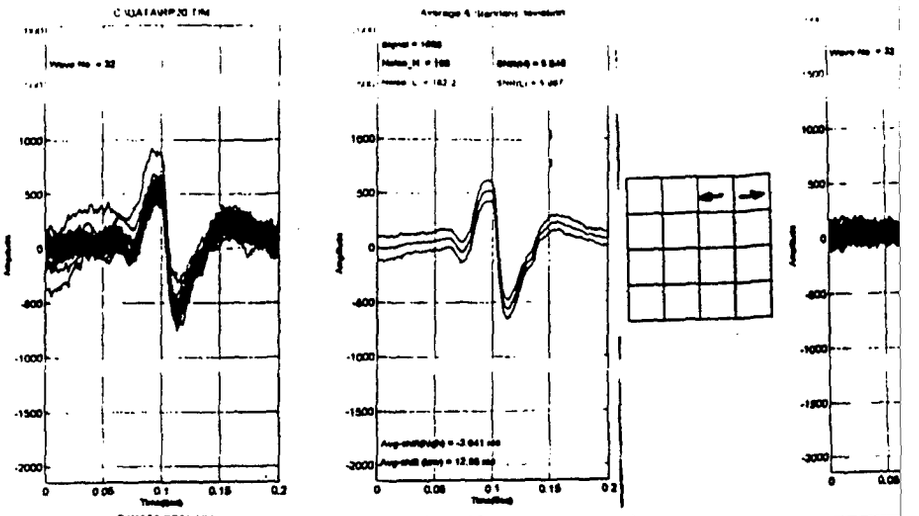
T 5'3" WEIGHT 123 LB

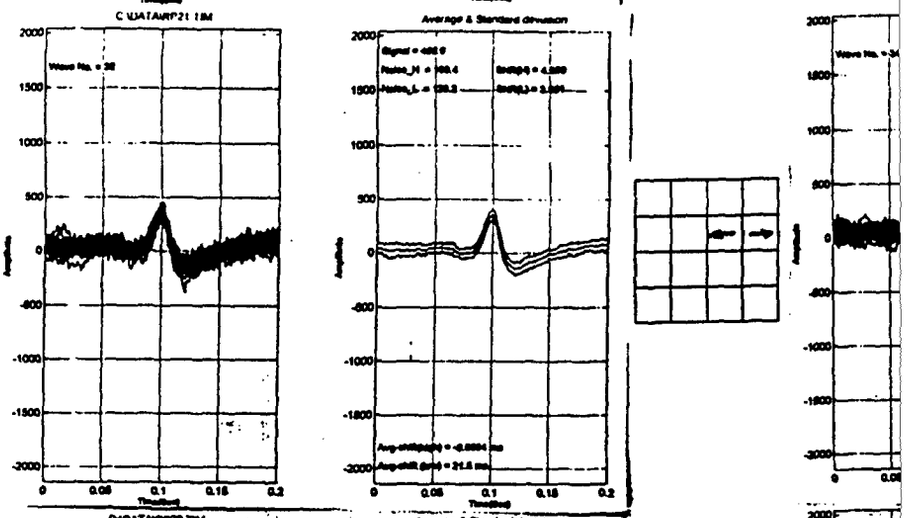


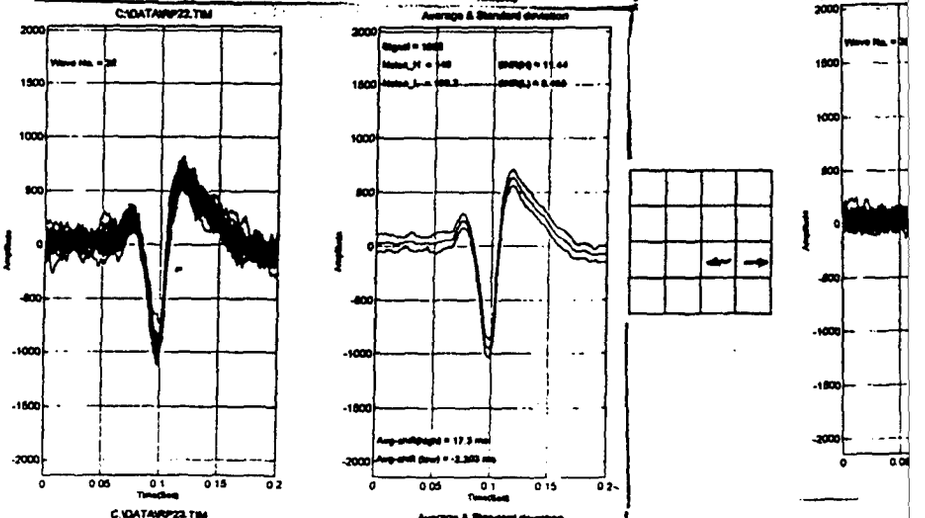


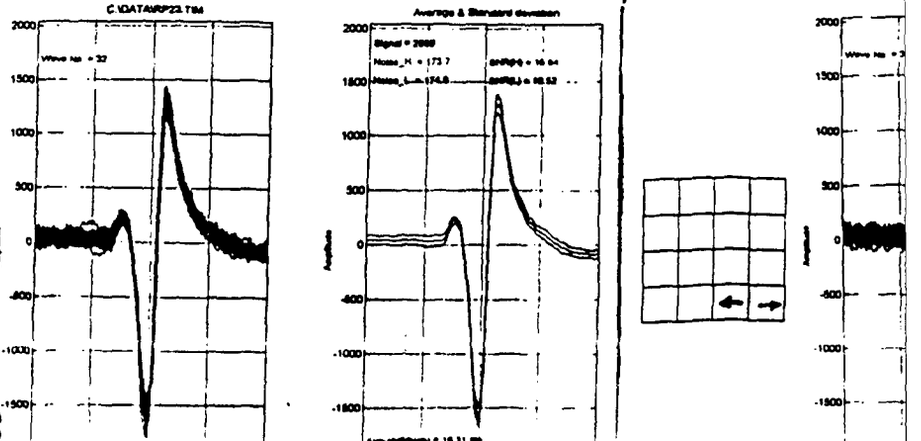




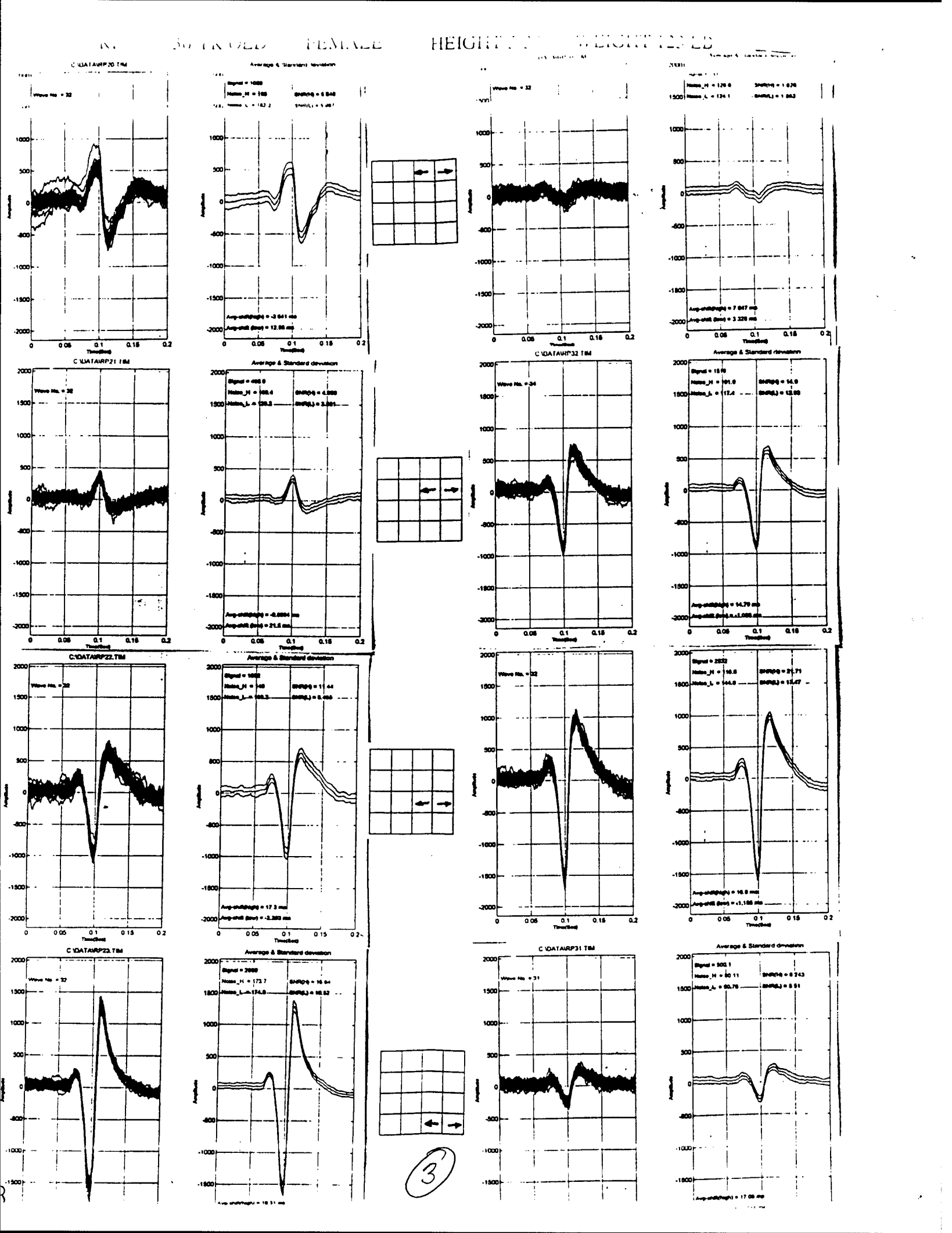








(2) 18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Average & Standard deviation
C:\DATA\RP21.TIM
Average & Standard deviation
C:\DATA\RP22.TIM
Average & Standard deviation
C:\DATA\RP23.TIM
Average & Standard deviation
C:\DATA\RP31.TIM
Average & Standard deviation
C:\DATA\RP32.TIM
Average & Standard deviation
Wave No. = 32
Wave No. = 34
Wave No. = 31
Amplitude
Time(Sec)
3

Subject III CR 38 YR OLD FEMALE HEIGHT 5 10 WEIGHT 150 LB

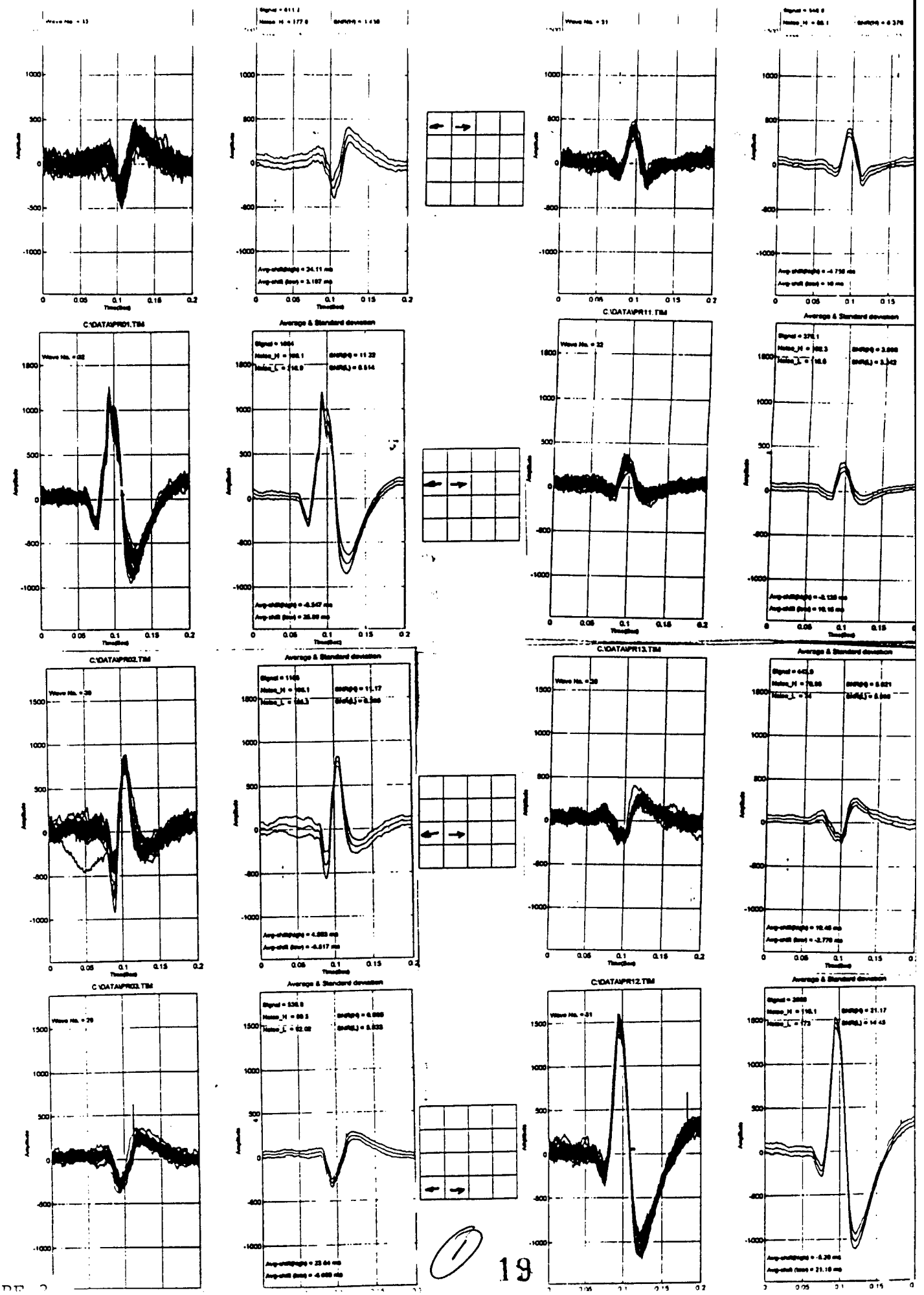
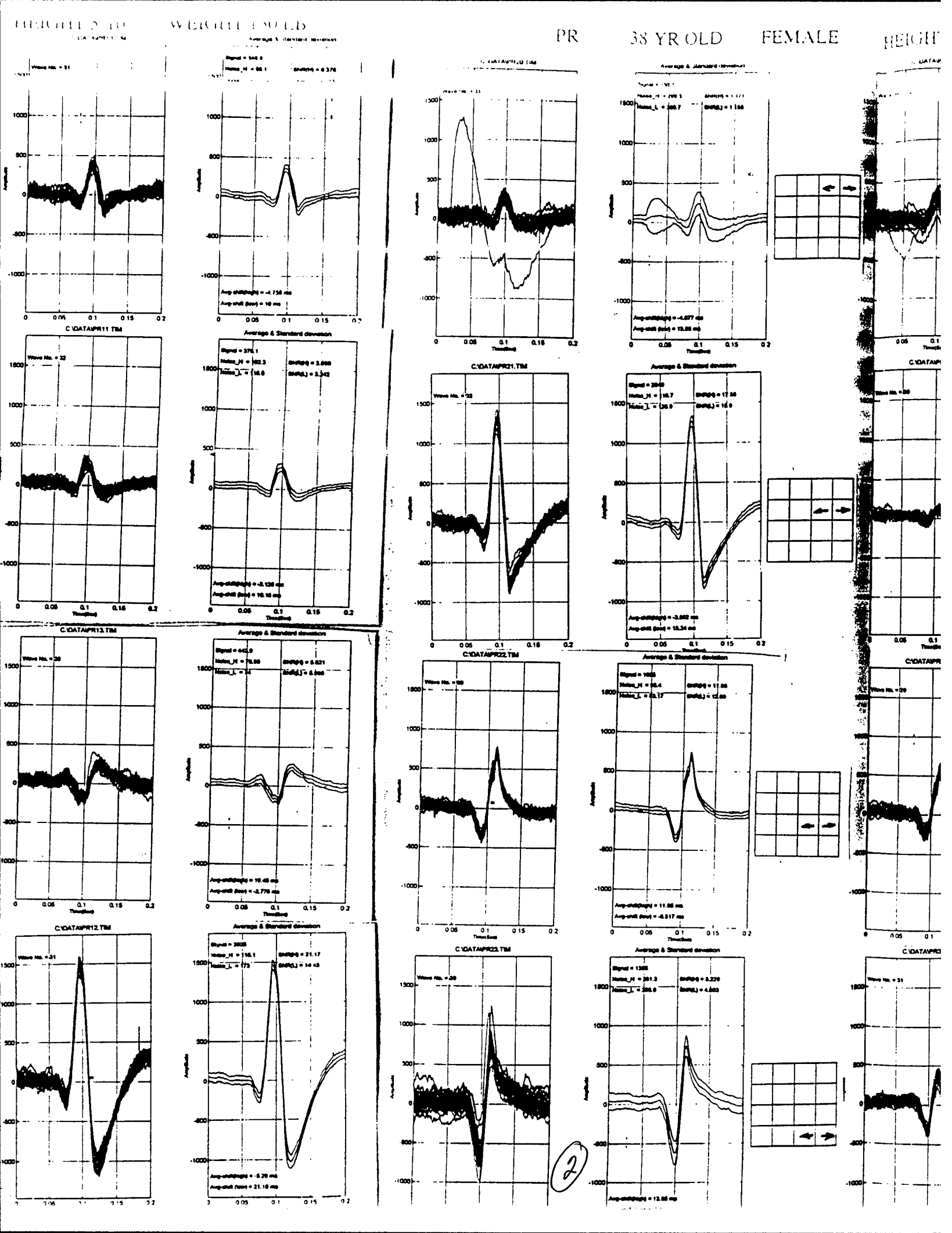


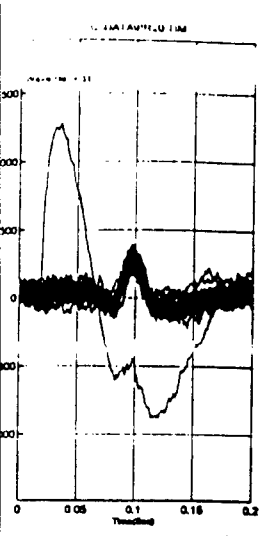
FIGURE 2

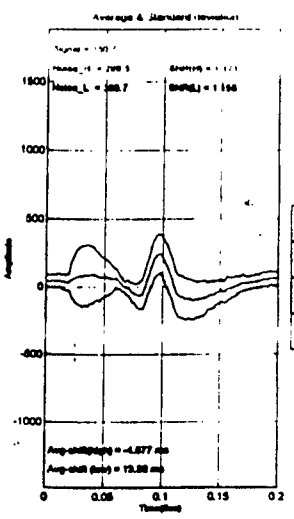
HEIGHT 5 10 WEIGHT 150 LB PR 38 YR OLD FEMALE HEIGH

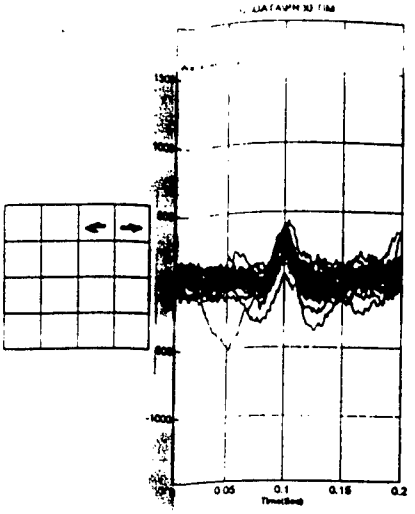


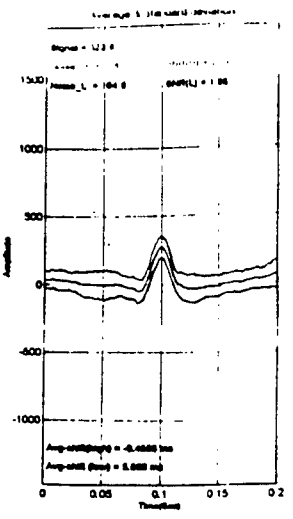
2

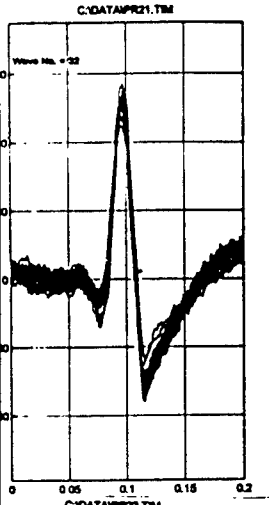
PR 38 YR OLD FEMALE HEIGHT 5'10" WEIGHT 130 LB

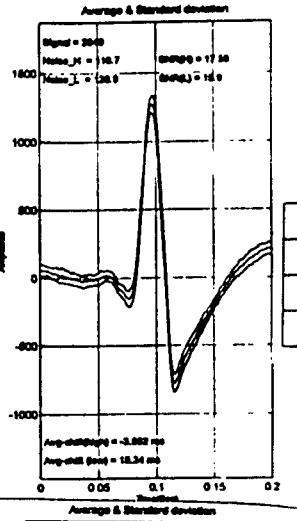


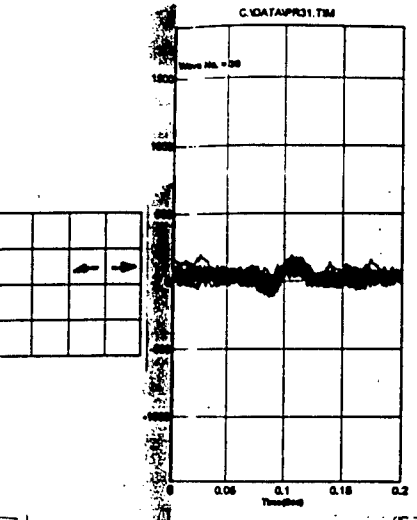


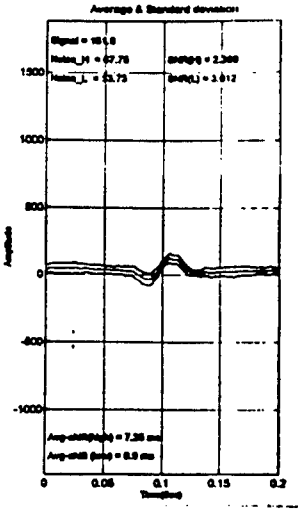


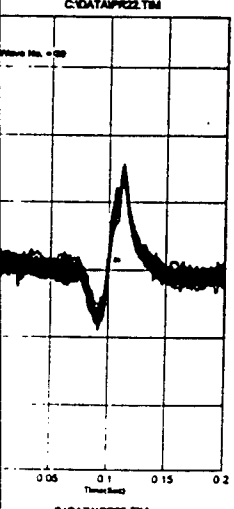


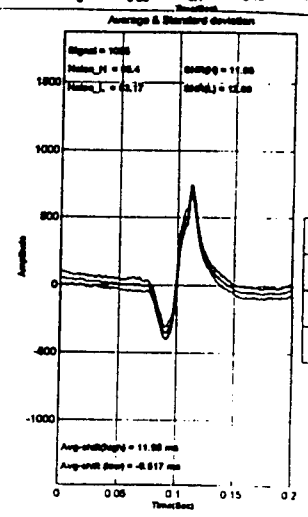


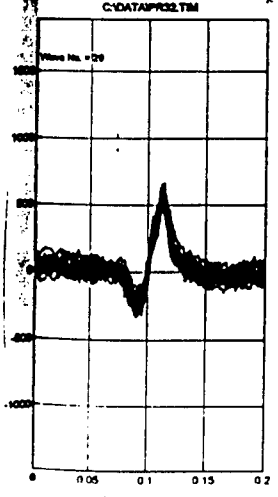


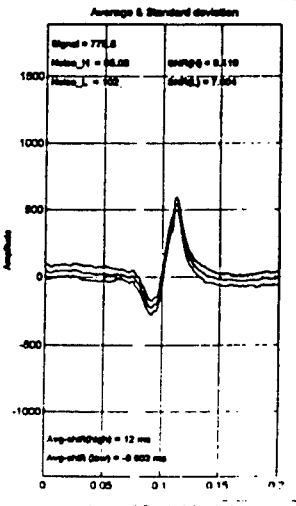


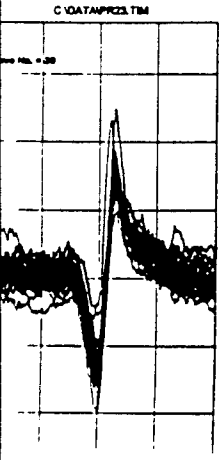


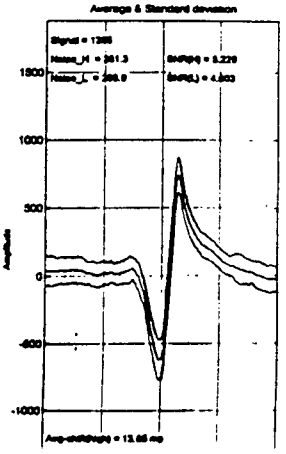


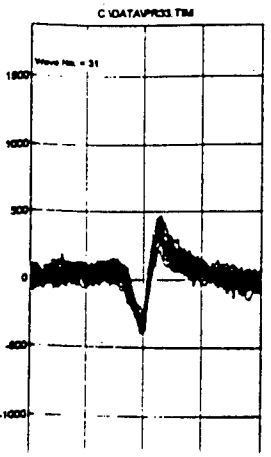


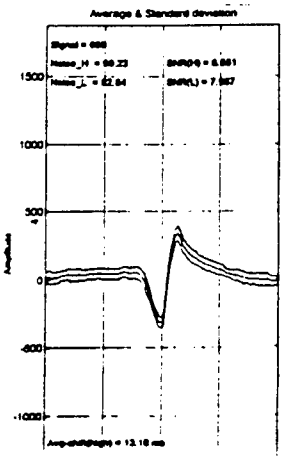












3

Subject IV [illegible] YR OLD MALE HEIGHT 5'3" WEIGHT 155 LB

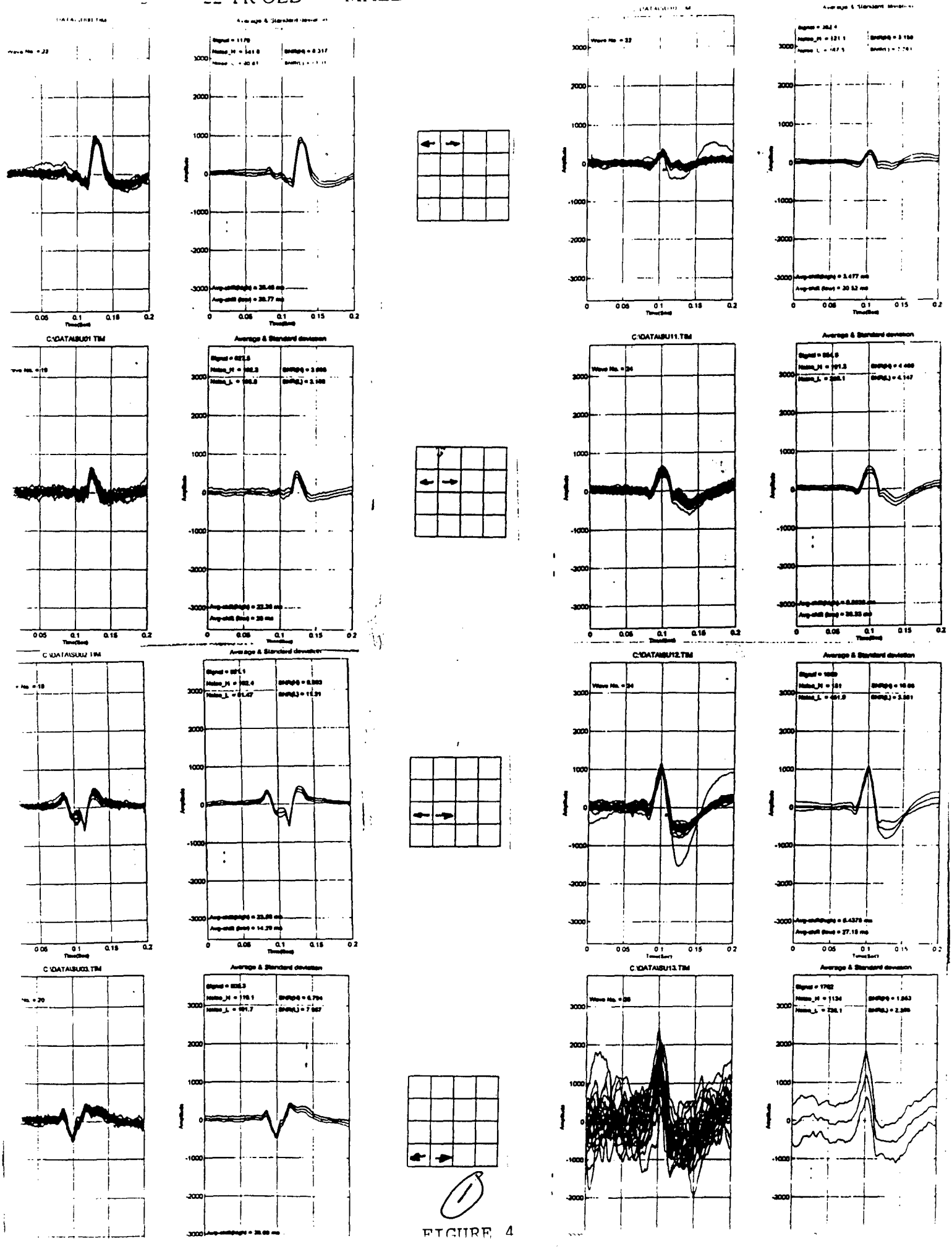
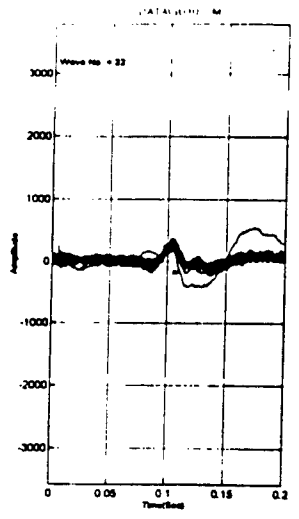
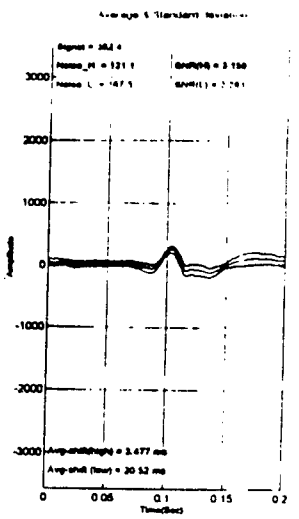
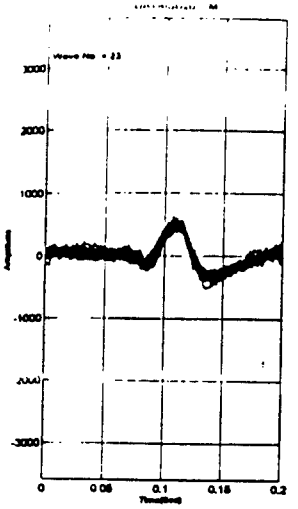


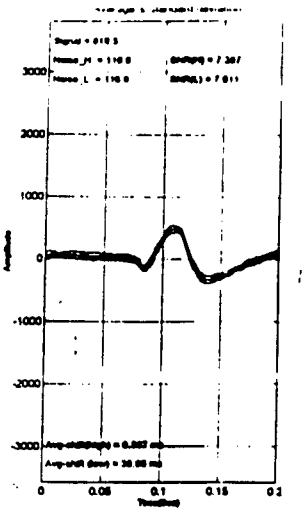
FIGURE 4

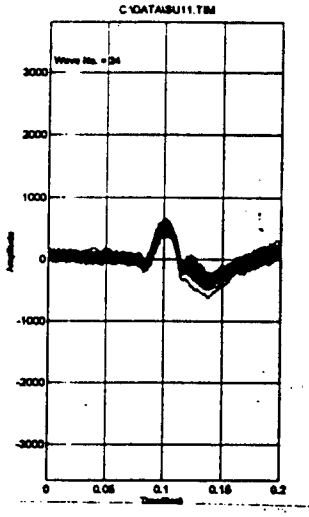
HEIGHT 5'3" WEIGHT 155 LB SU 22 YR OLD MALE

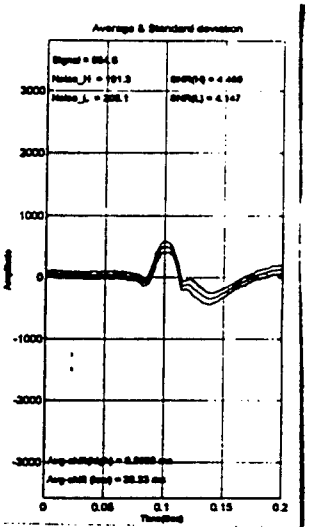


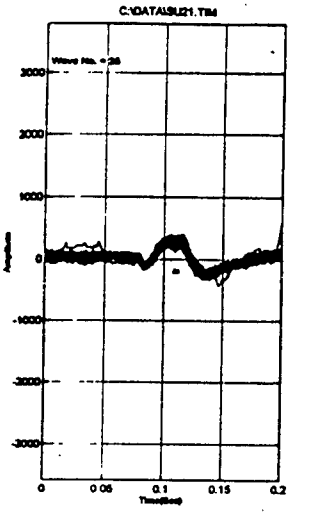


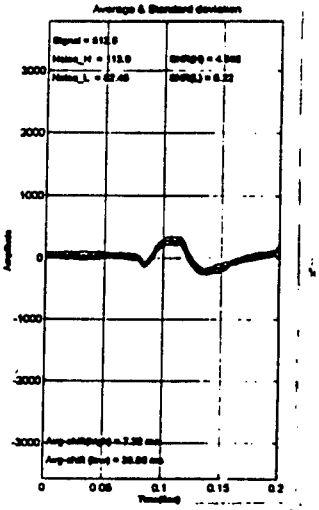


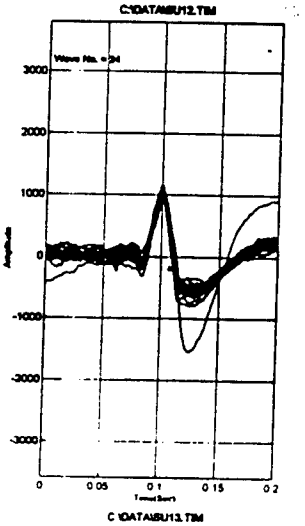


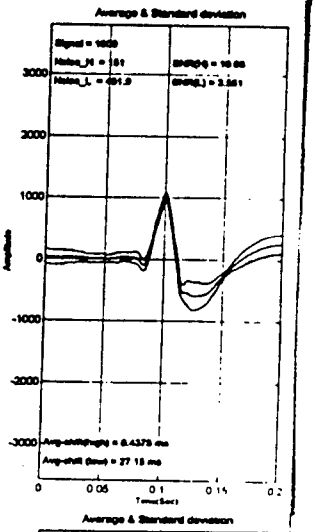


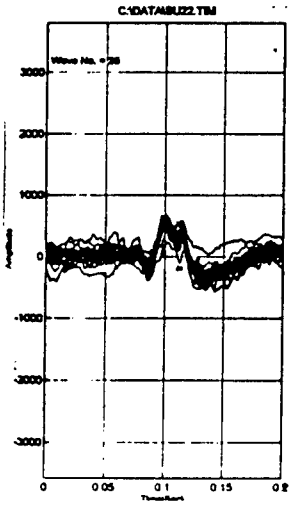


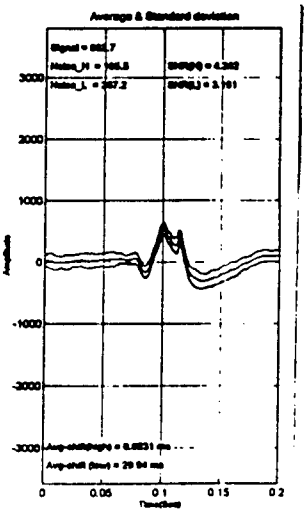


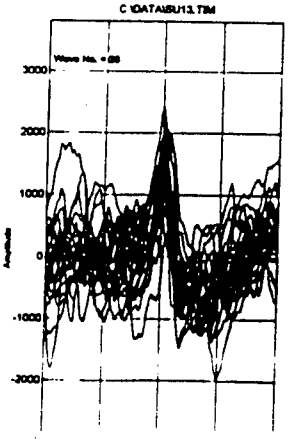


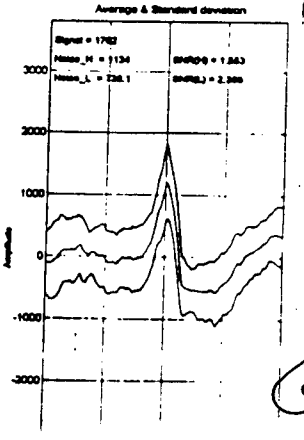


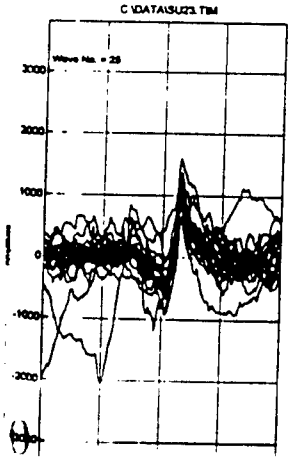


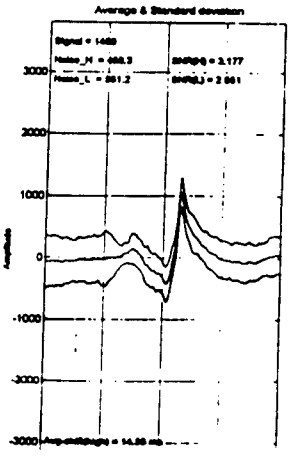






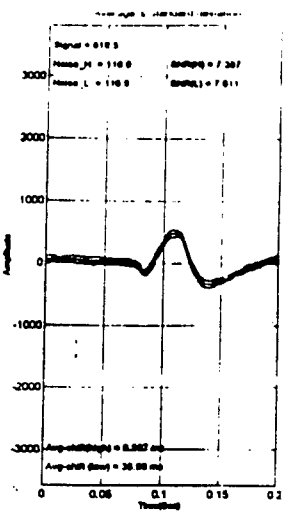


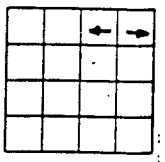


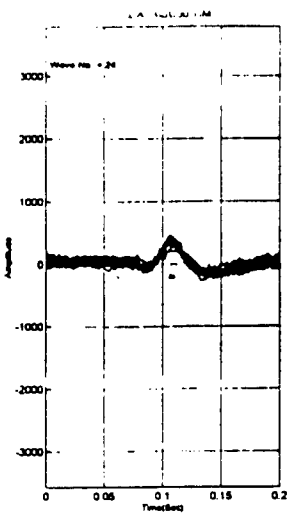


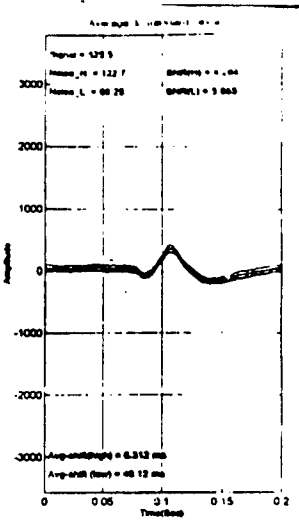
(2) 20

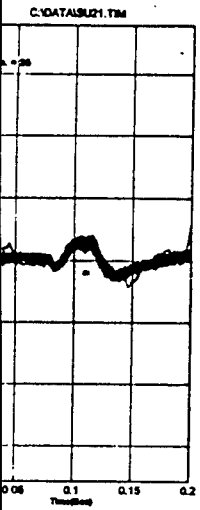
SU 22 YR OLD MALE HEIGHT [illegible] WEIGHT [illegible] LB

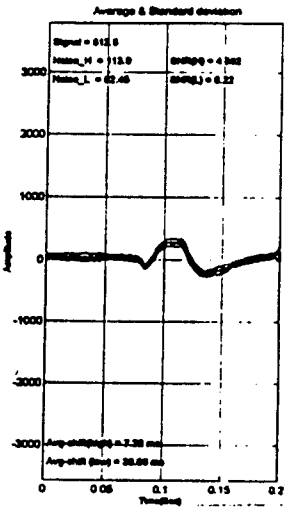


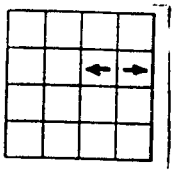


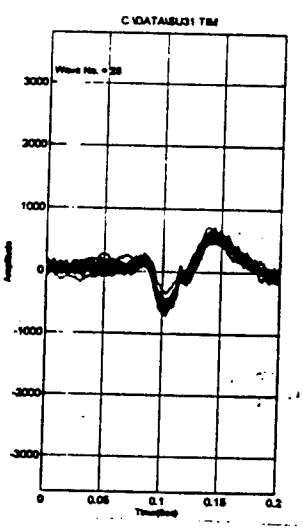


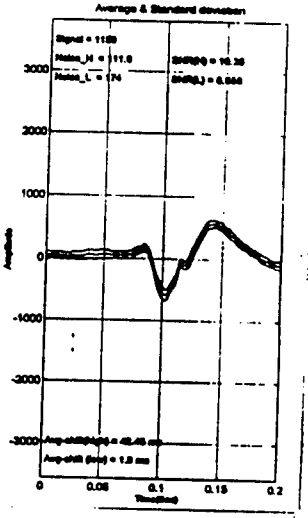


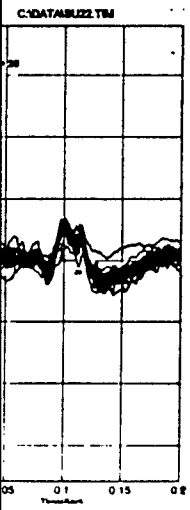


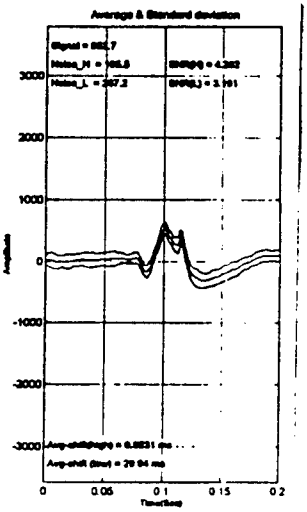


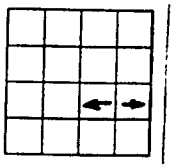


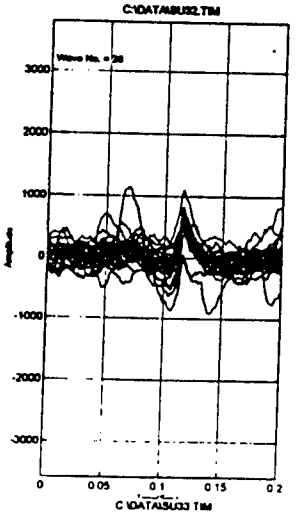


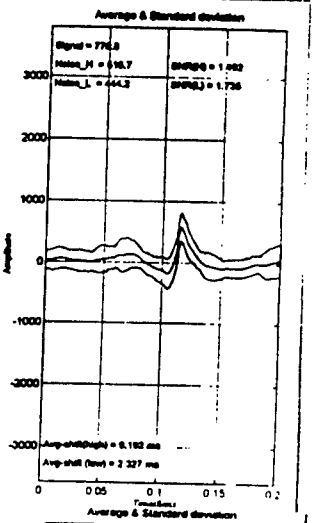


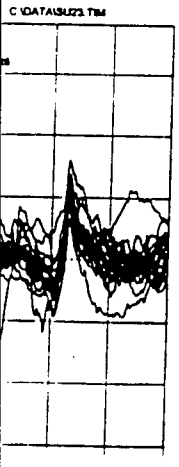


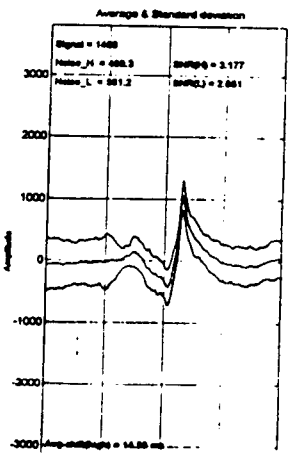


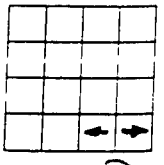


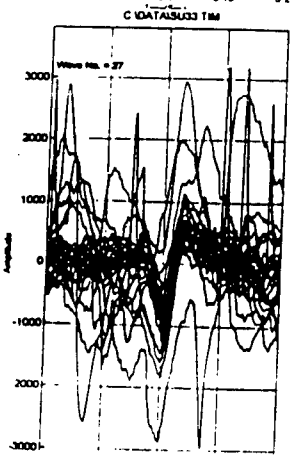


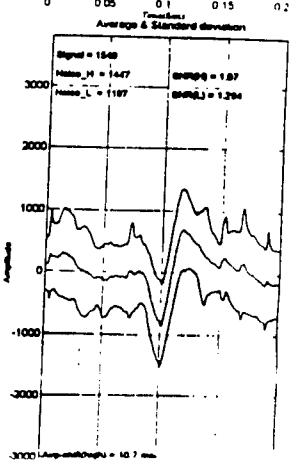






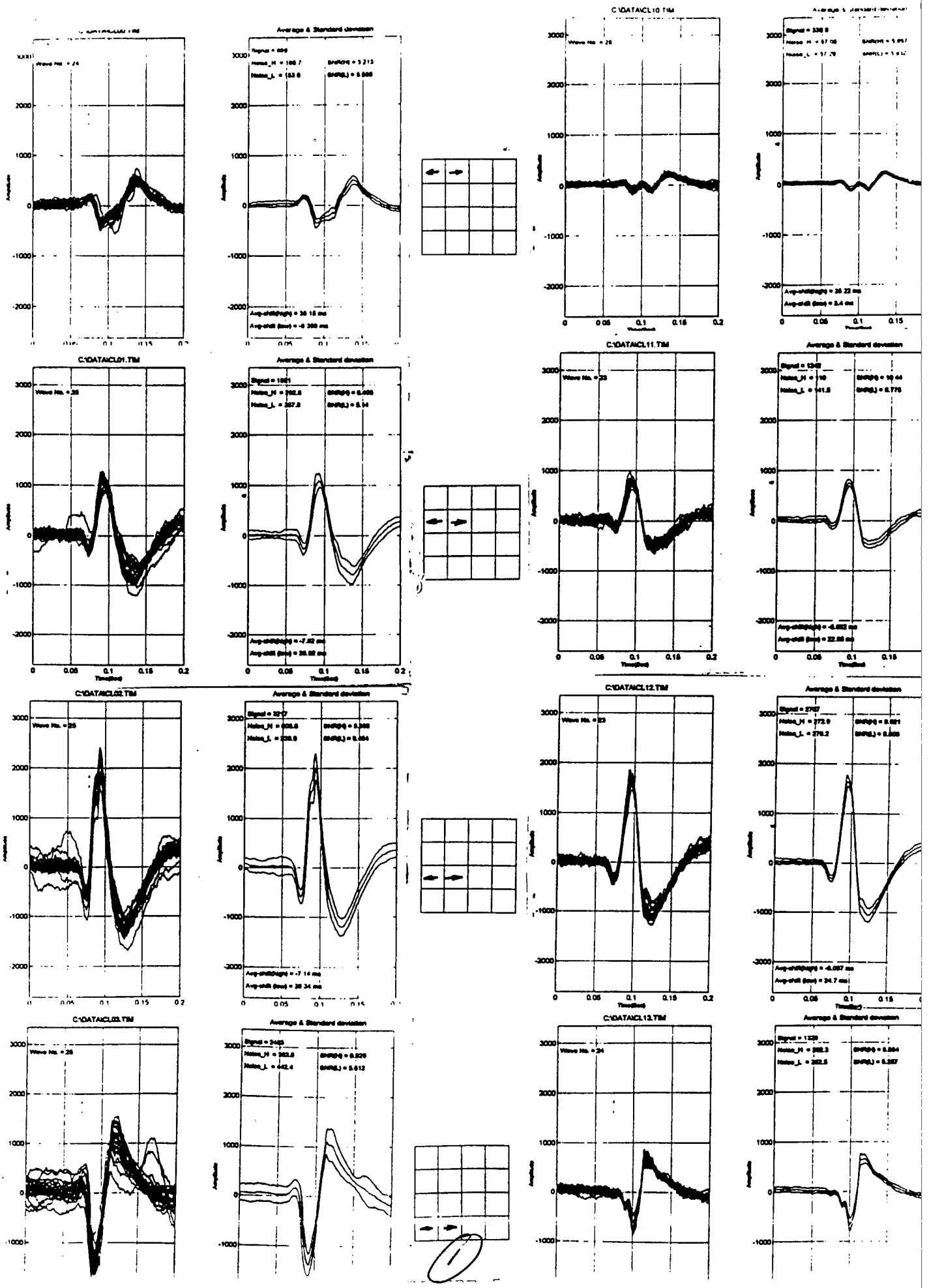




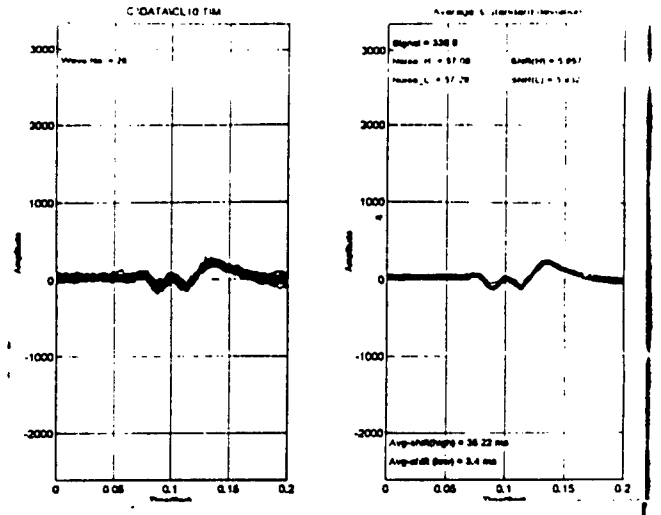


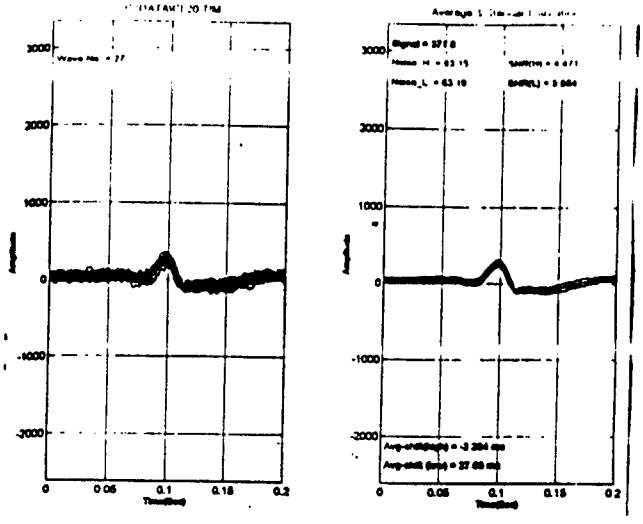
3

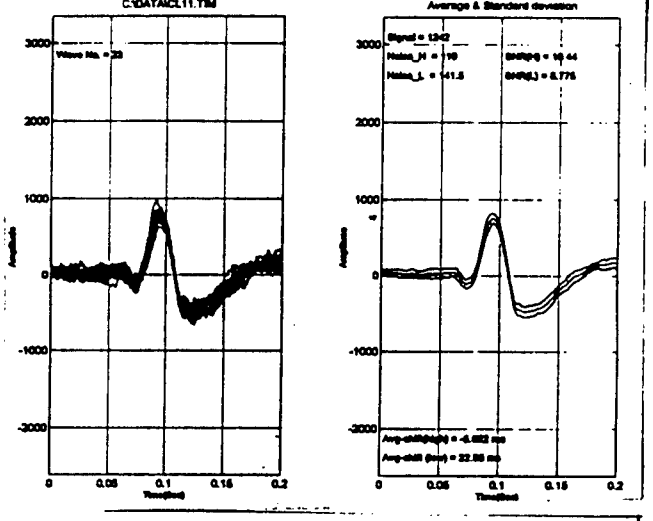
Subject V CL 35 YR OLD MALE HEIGHT 5'3" WEIGHT 136 LB

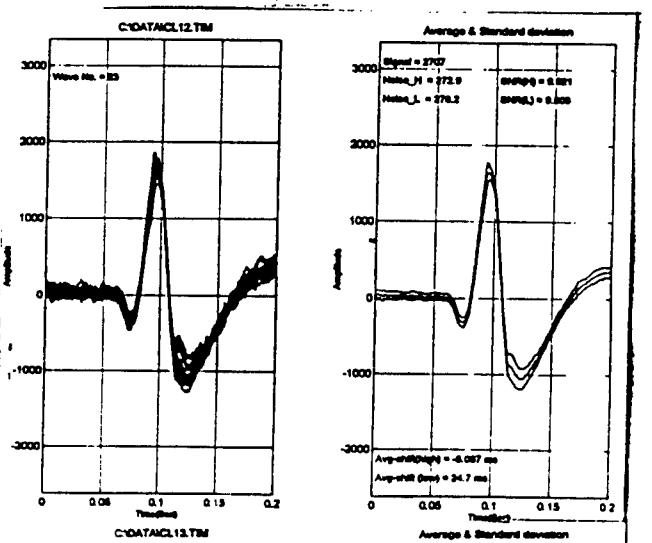


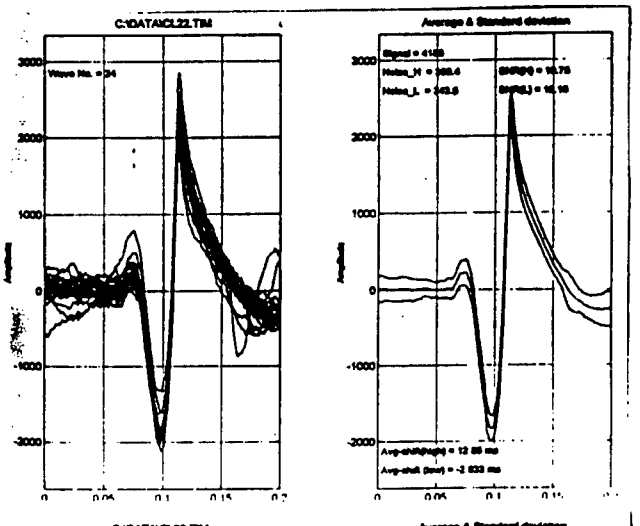
LE HEIGHT 5'3" WEIGHT 136 LB CL 35 YR OLD MALE

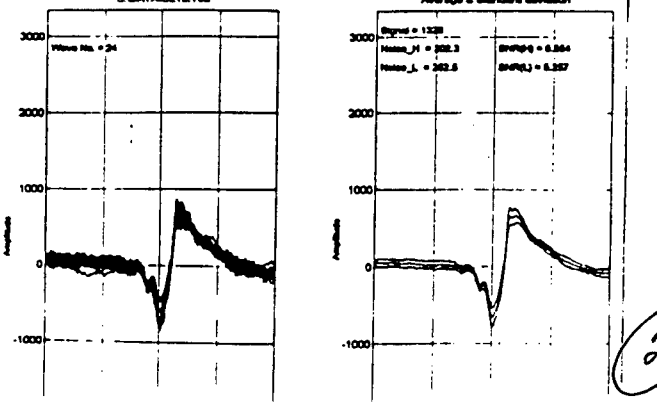


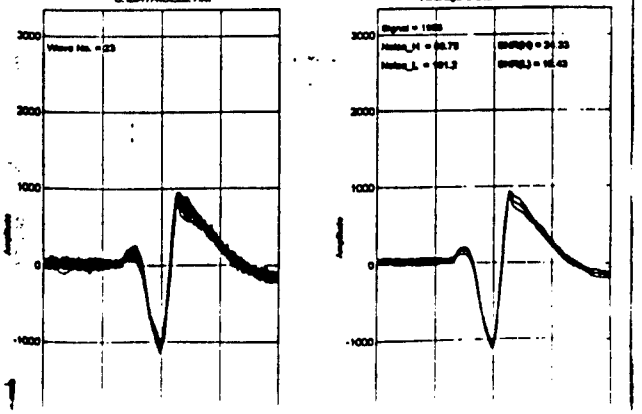




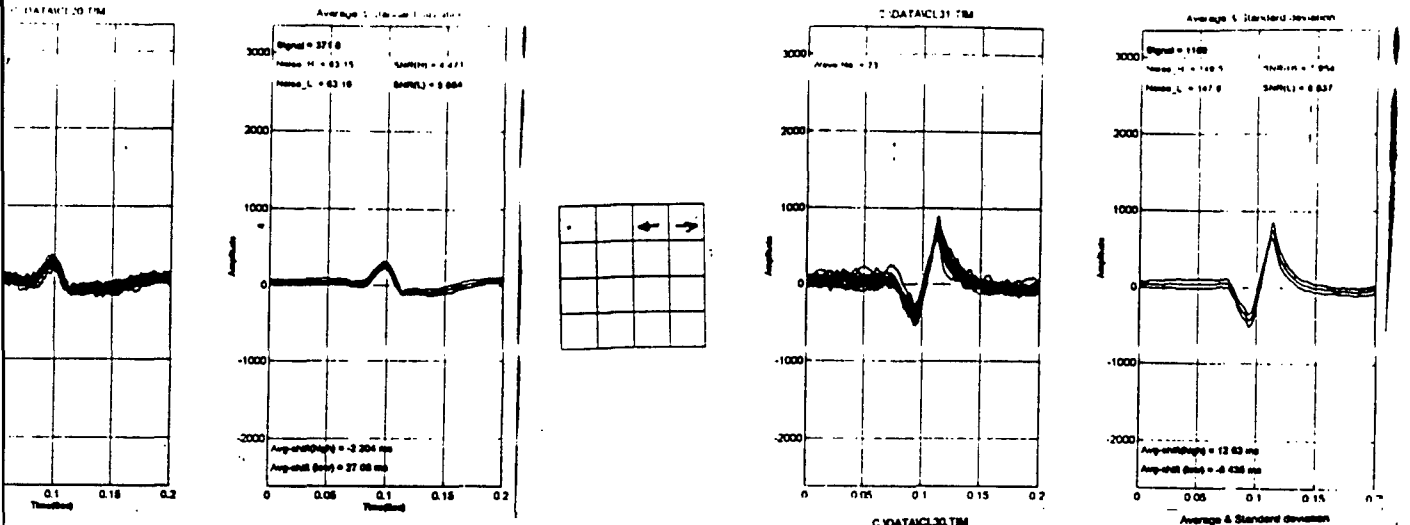


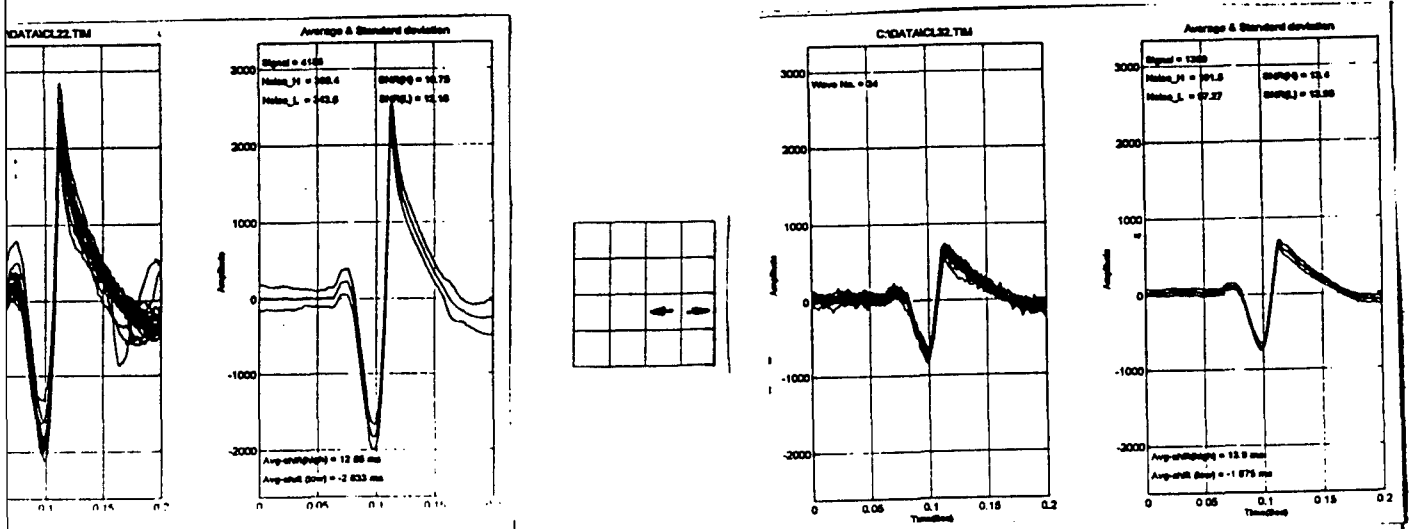


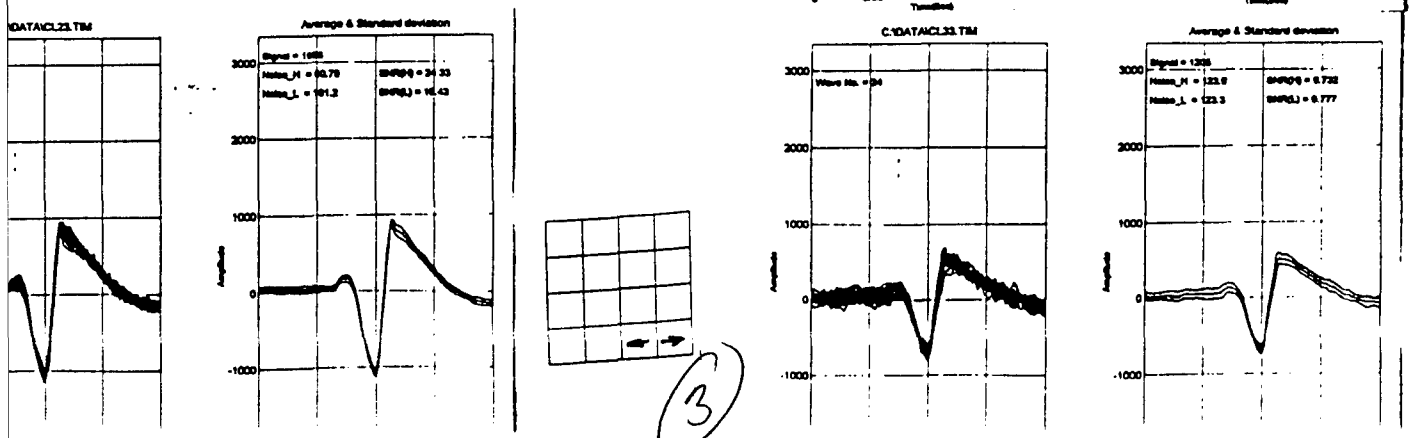




CL 35 YR OLD MALE HEIGHT 5'3" WEIGHT 136 LB







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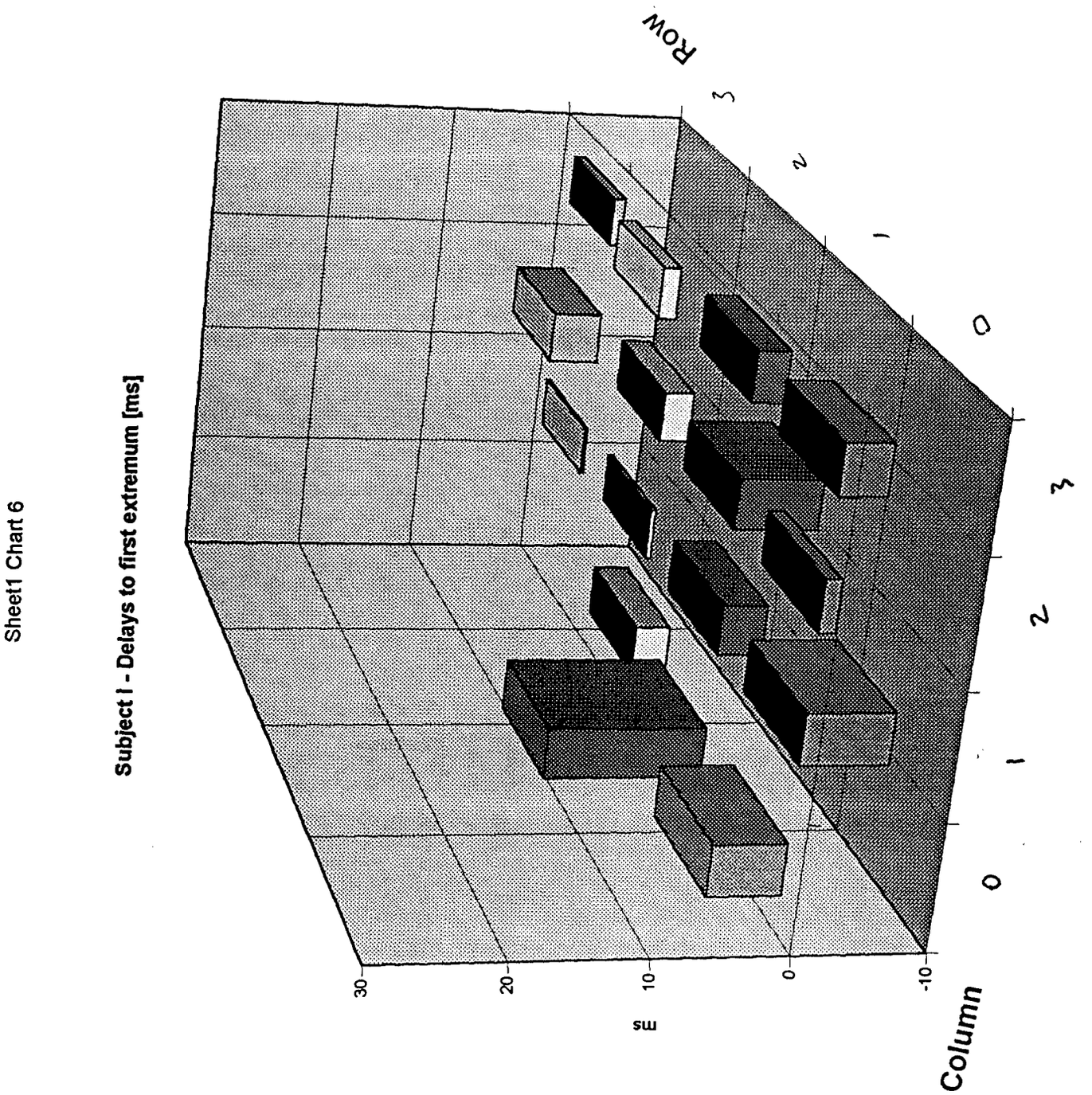

Sheet1 Chart 6
Subject I - Delays to first extremum [ms]
ms
30
20
10
0
-10
Column
0
1
2
3
Row
0
1
2
3

FIGURE 6A

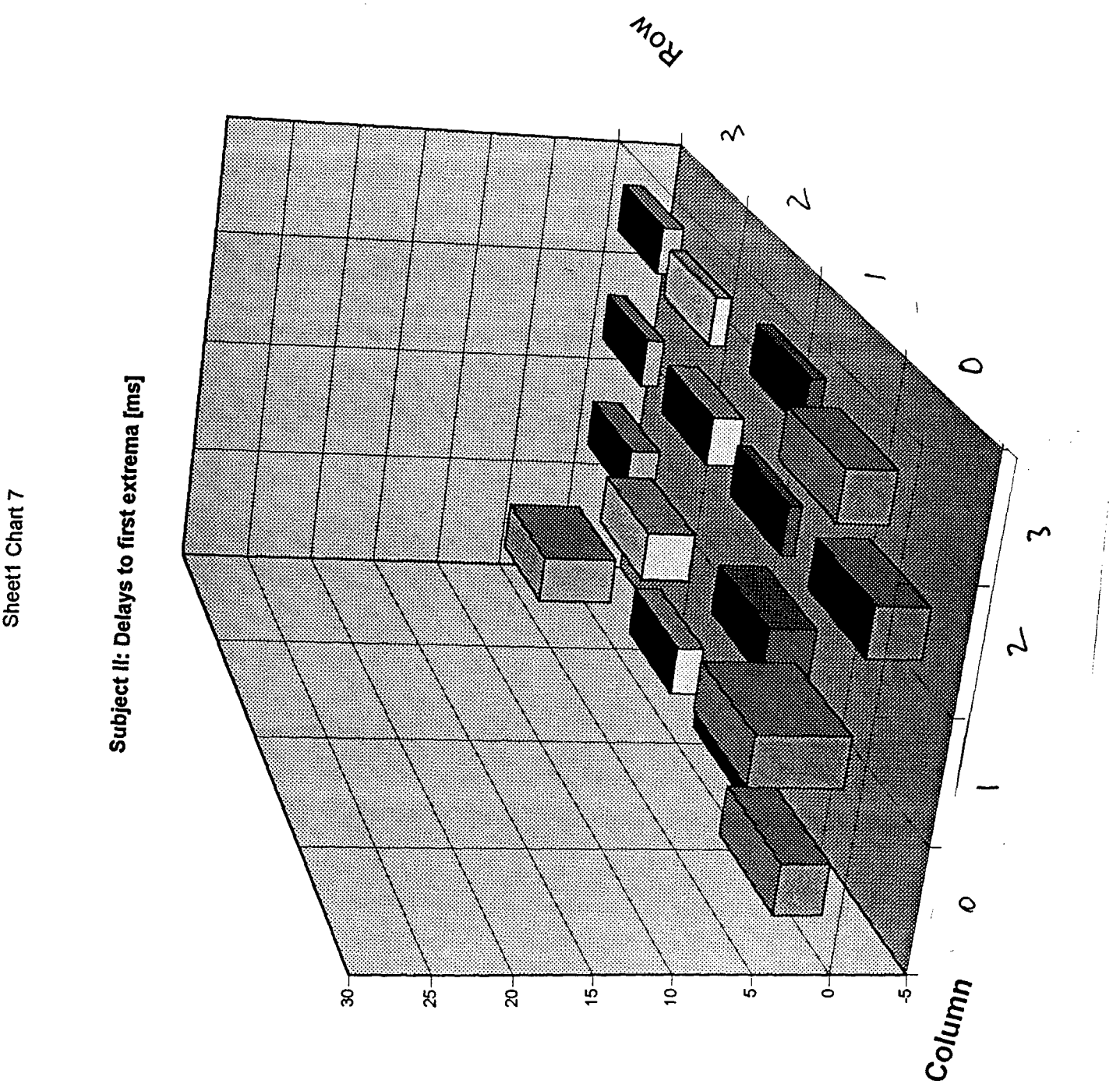

Sheet1 Chart 7
Subject II: Delays to first extrema [ms]
30
25
20
15
10
5
0
-5
Column
0
1
2
3
Row
0
1
2
3

FIGURE 6B

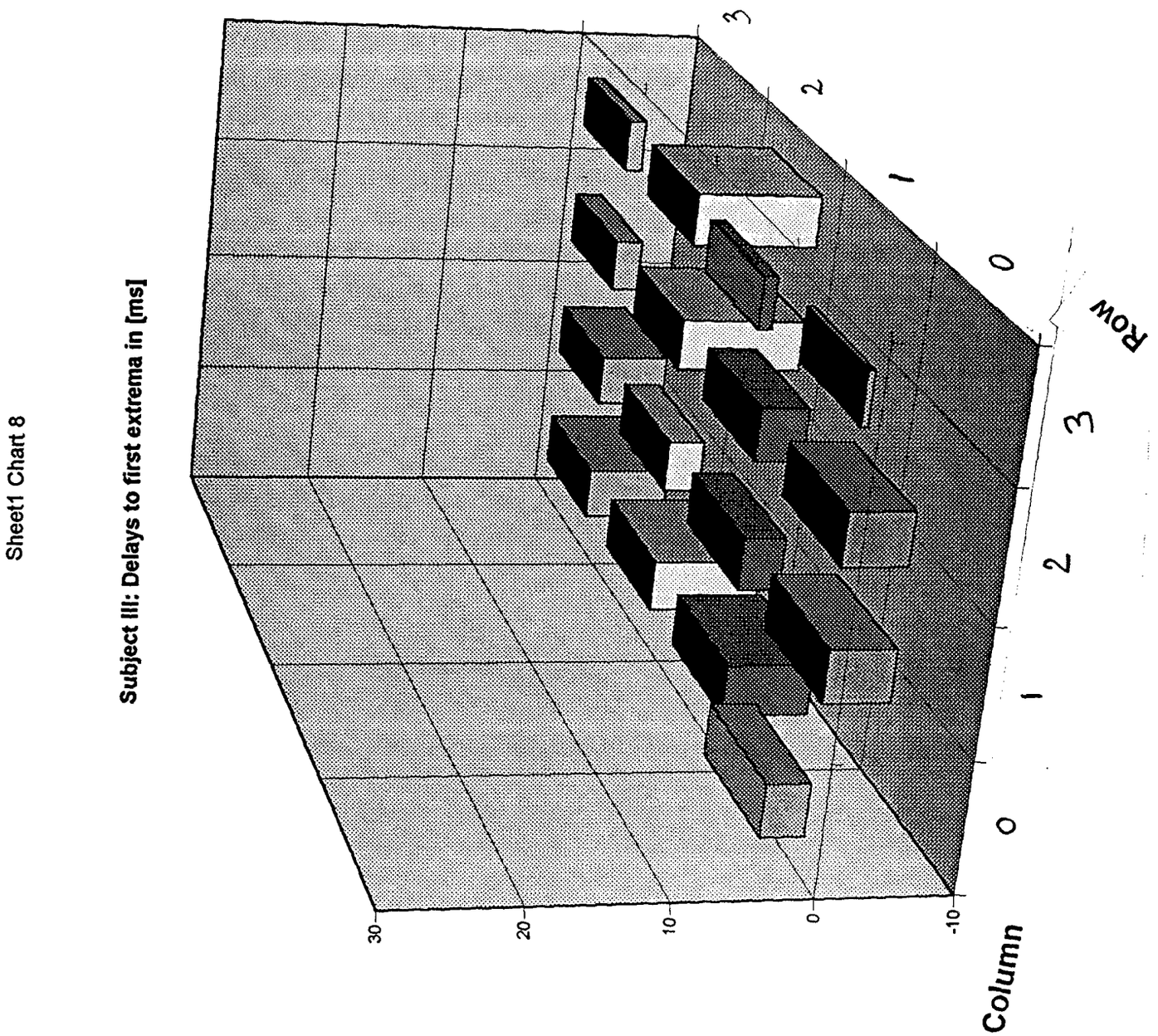

Sheet1 Chart 8
Subject III: Delays to first extrema in [ms]
30
20
10
0
-10
Column
0
1
2
3
Row
0
1
2
3

FIGURE 6C

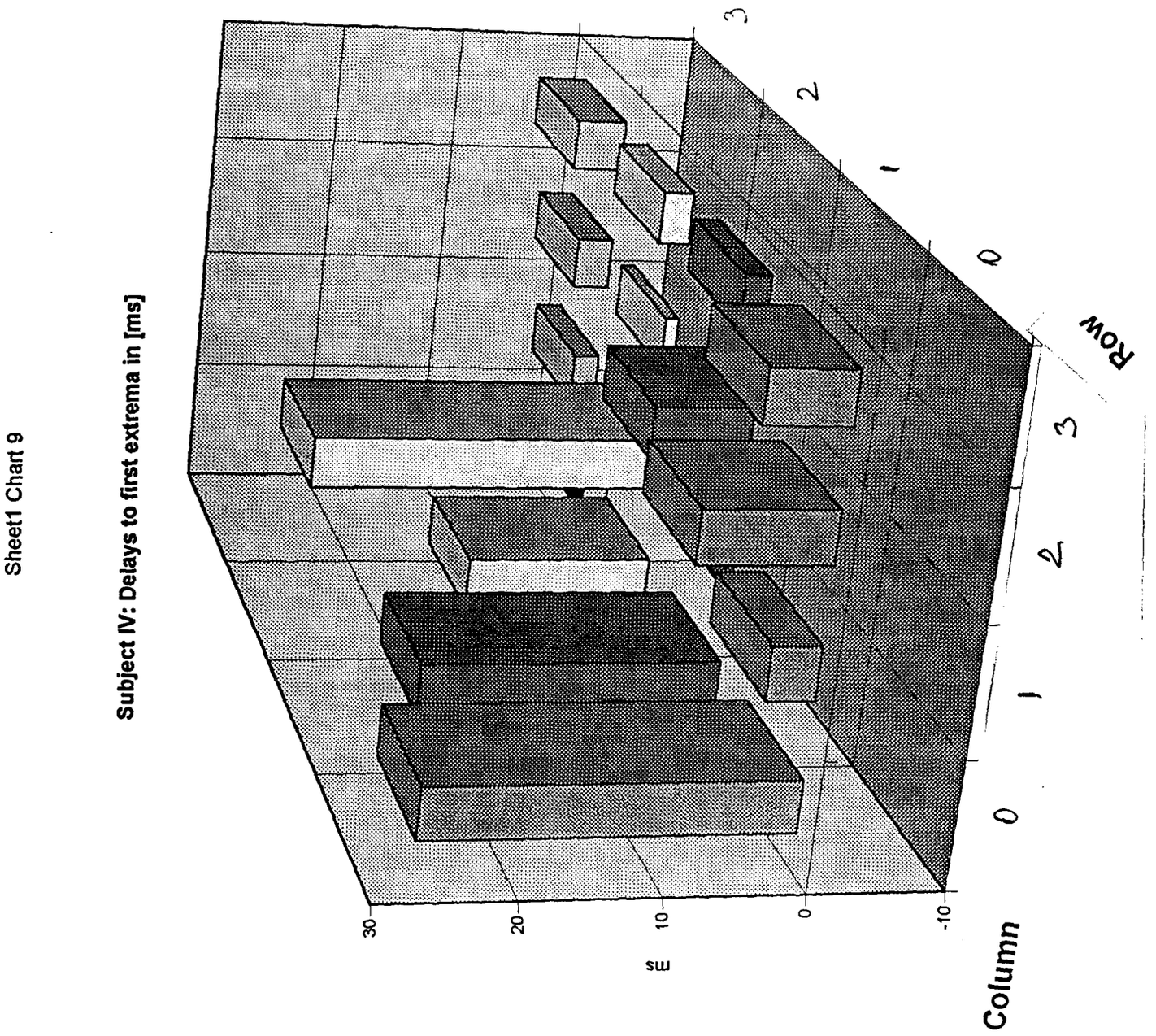
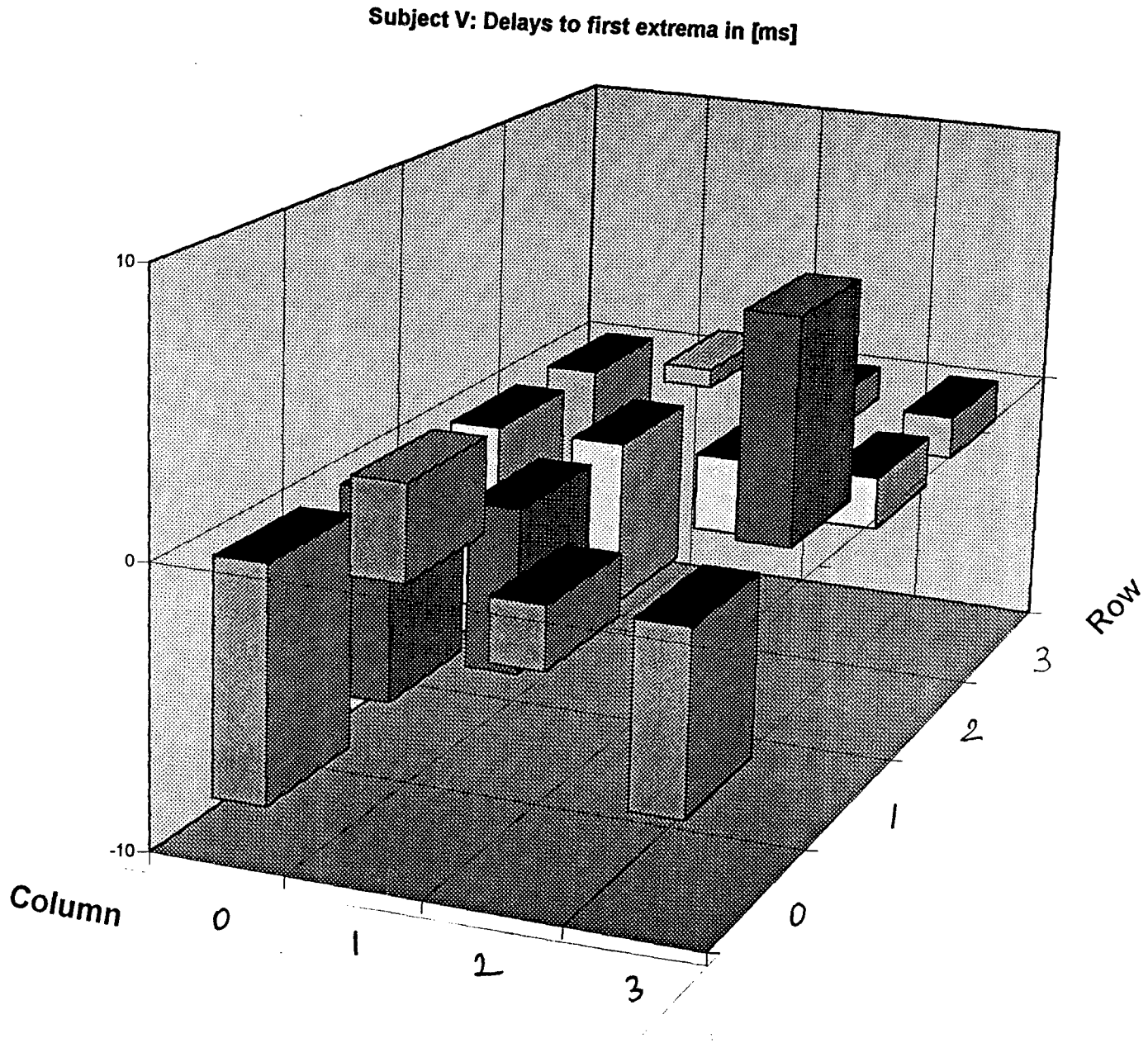

Sheet1 Chart 9
Subject IV: Delays to first extrema in [ms]
ms
30
20
10
0
-10
Column
0
1
2
3
Row
0
1
2
3

FIGURE 6D

FIGURE 6E


Subject V: Delays to first extrema in [ms]
10
0
-10
Column
0
1
2
3
Row
0
1
2
3

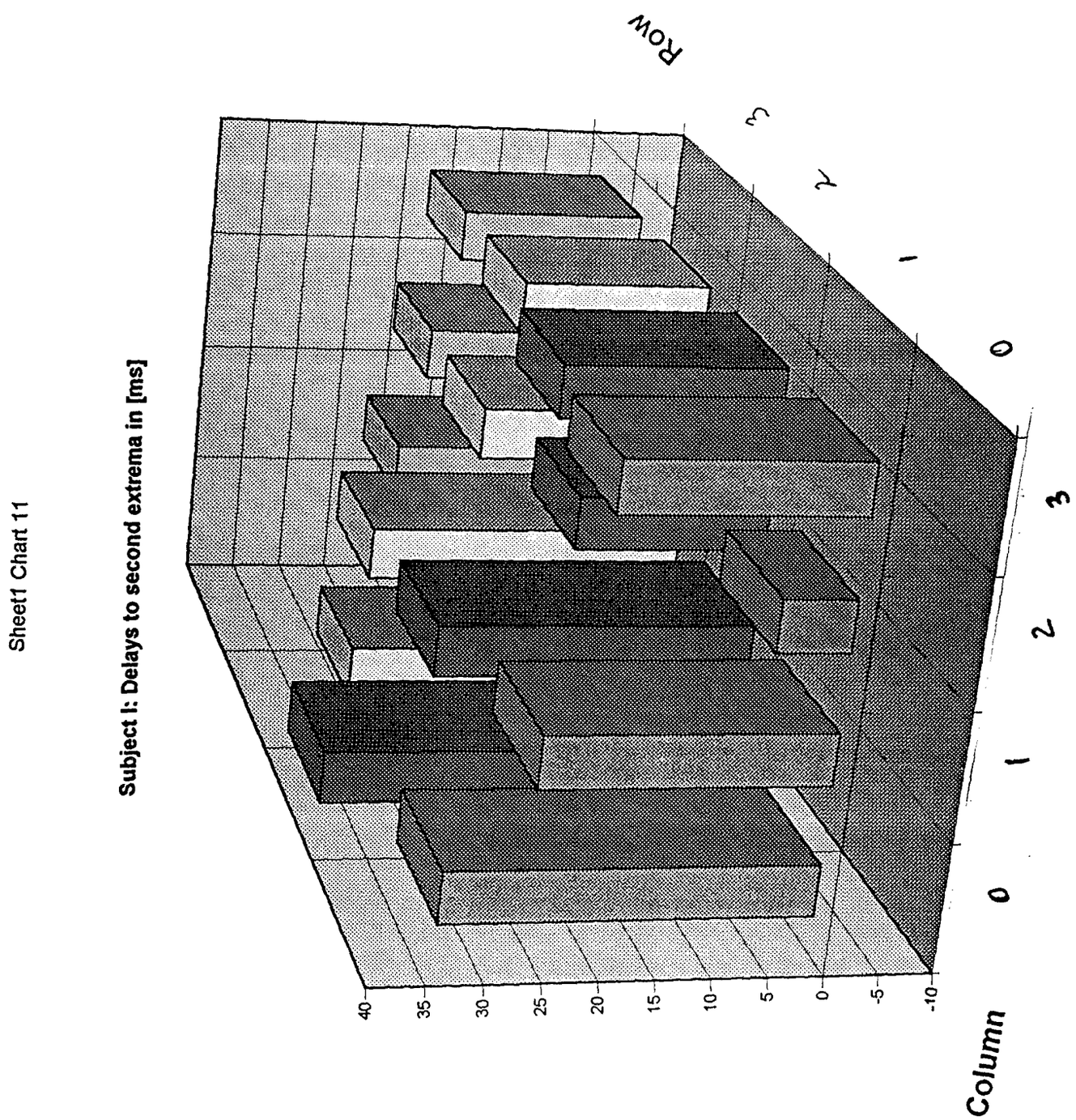

Sheet1 Chart 11
Subject I: Delays to second extrema in [ms]
Row
Column
0
1
2
3
40
35
30
25
20
15
10
5
0
-5
-10

FIGURE 7A

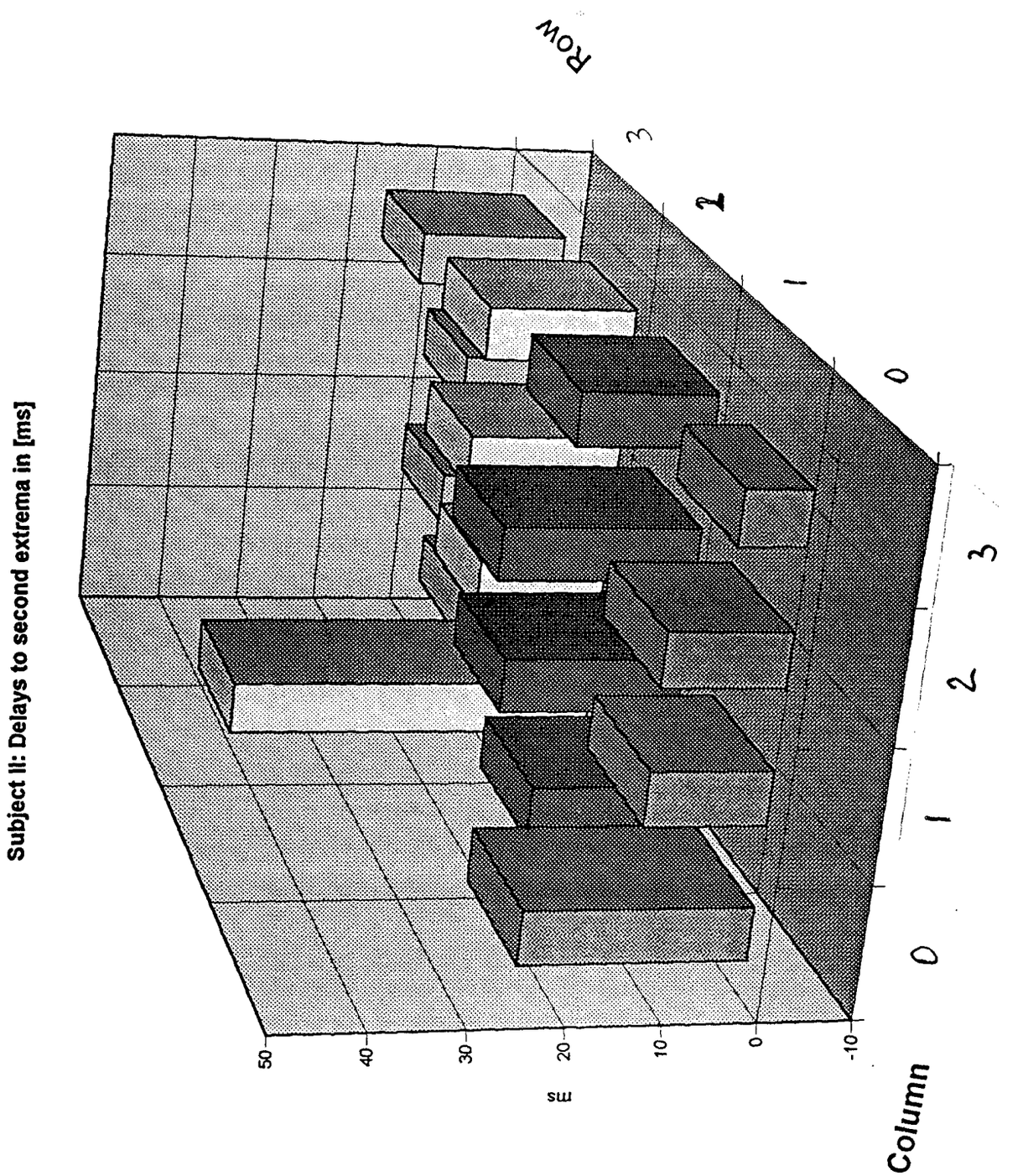

Sheet1 Chart 14
Subject II: Delays to second extrema in [ms]
ms
50
40
30
20
10
0
-10
Column
0
1
2
3
Row
0
1
2
3

FIGURE 7B

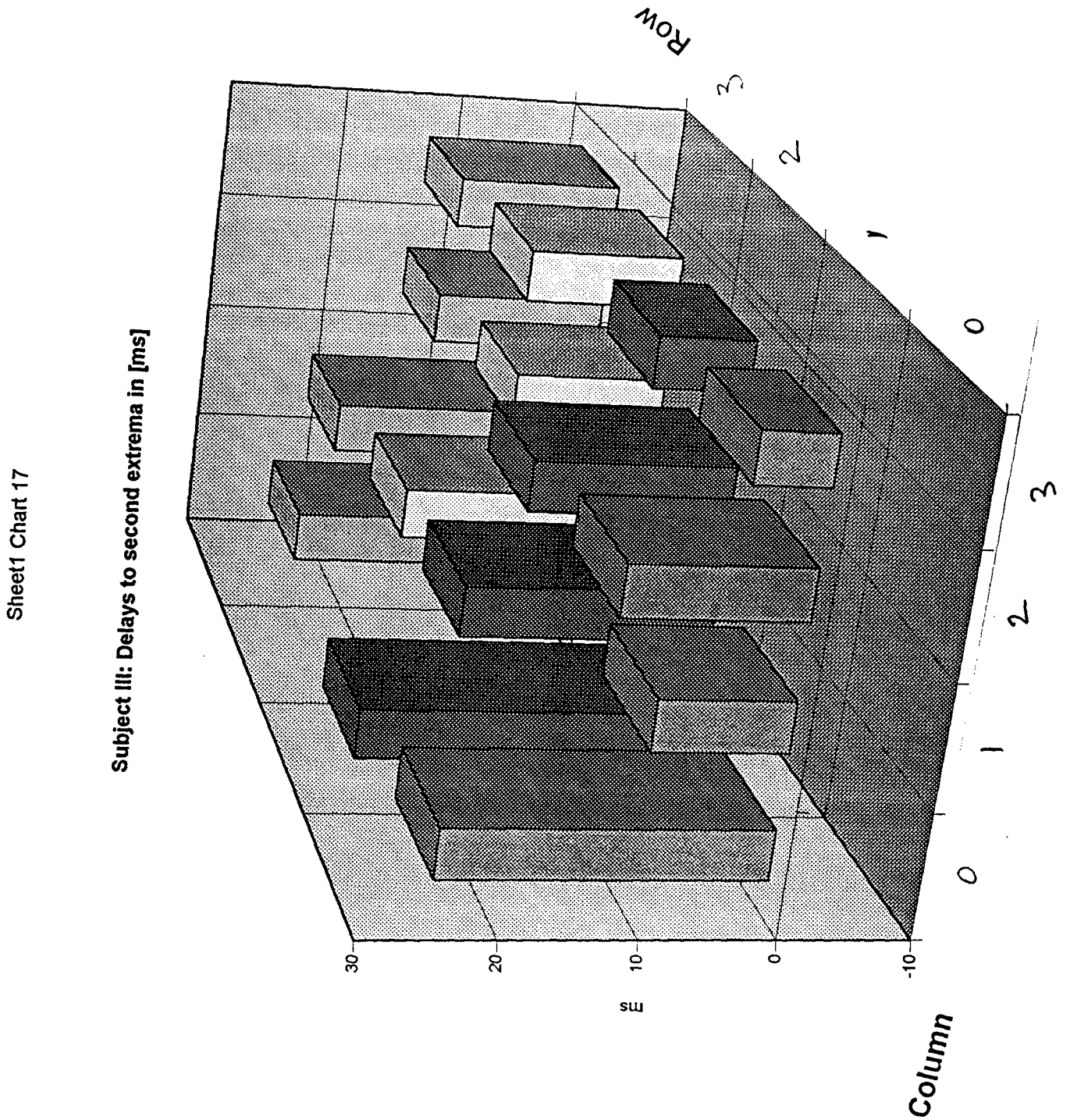

Sheet1 Chart 17
Subject III: Delays to second extrema in [ms]
Row
Column
ms
30
20
10
0
-10
0
1
2
3

FIGURE 7C

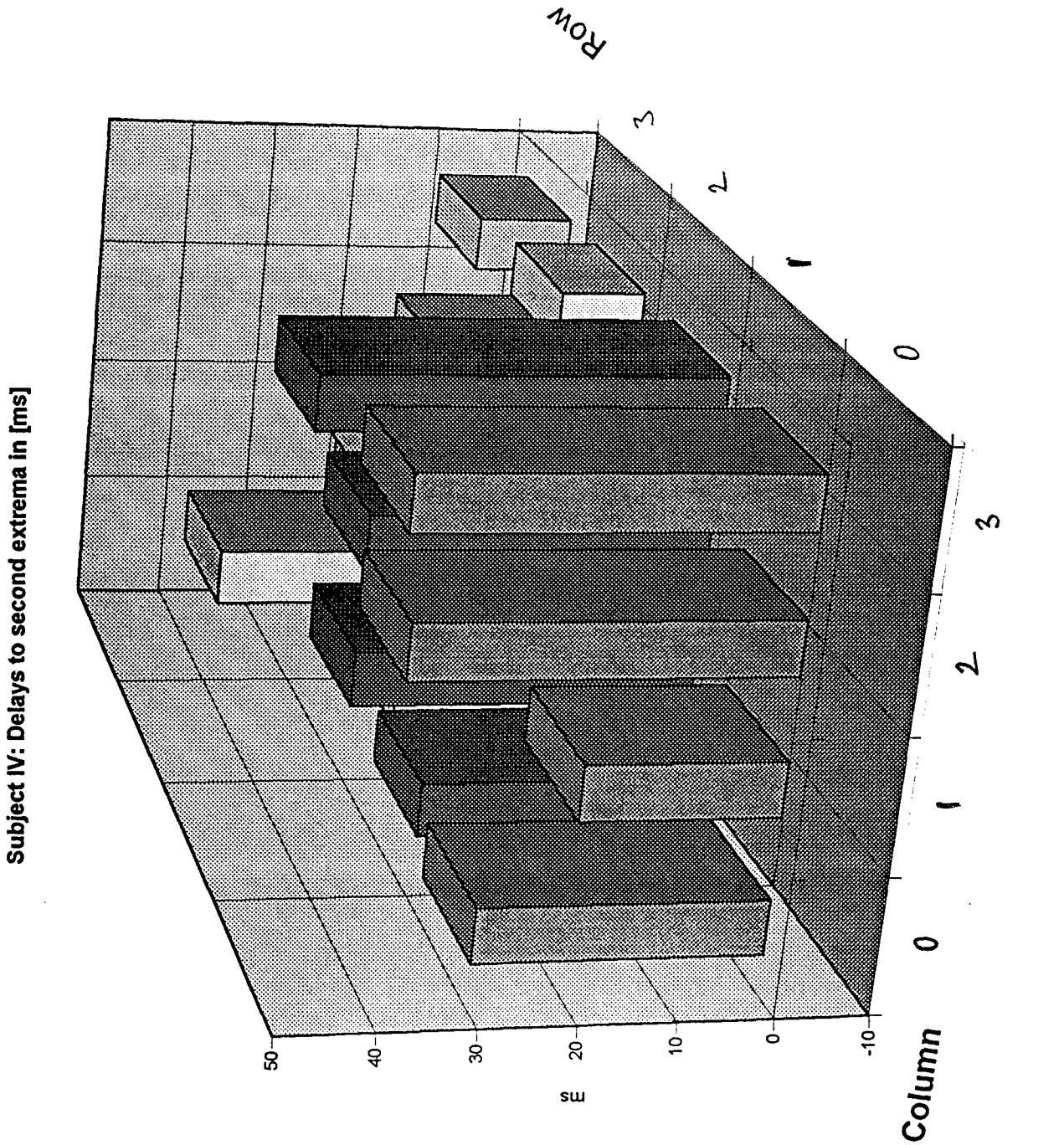

Sheet1 Chart 16
Subject IV: Delays to second extrema in [ms]
ROW
3
2
1
0
Column
0
1
2
3
ms
50
40
30
20
10
0
-10

FIGURE 7D

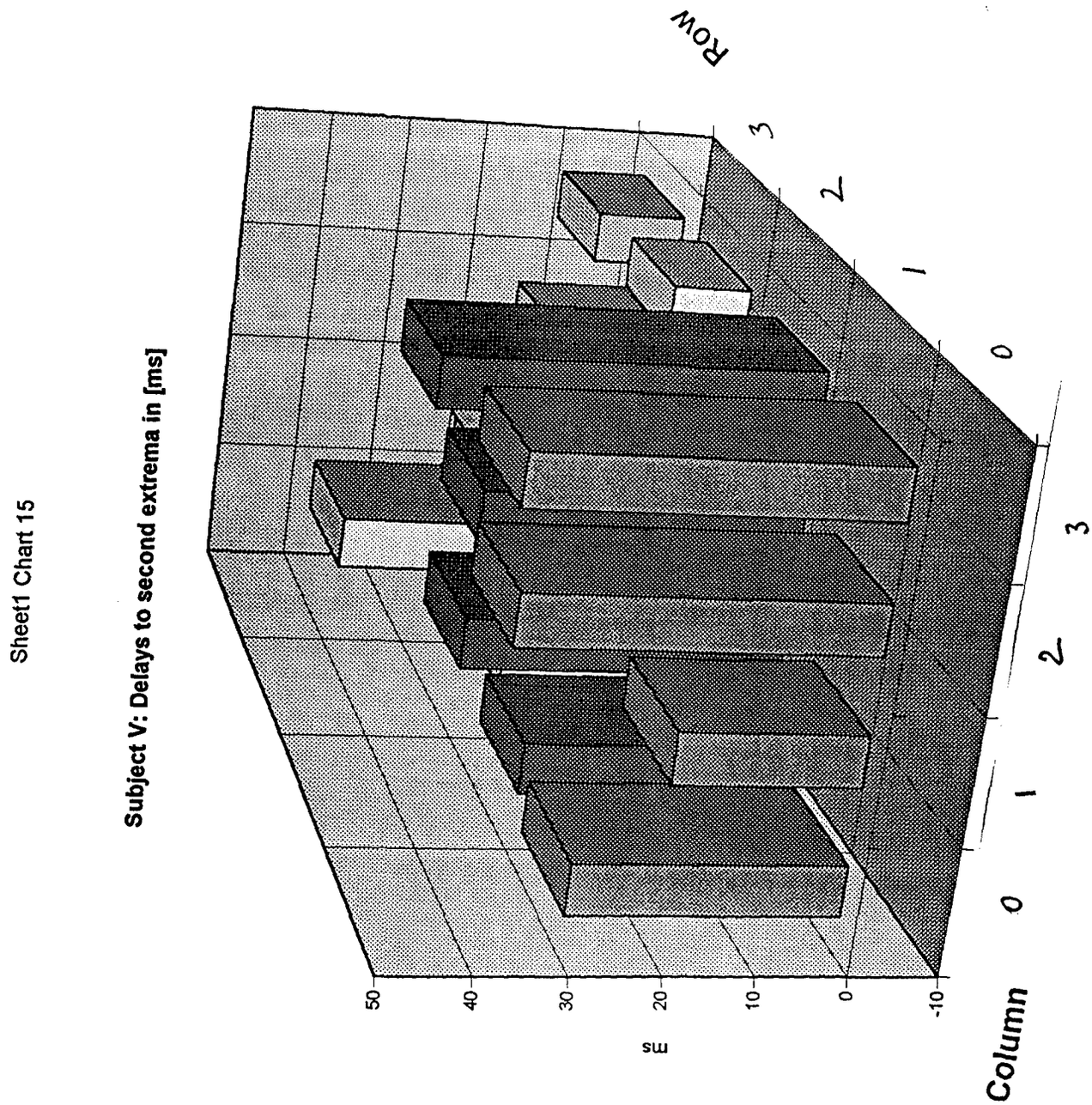
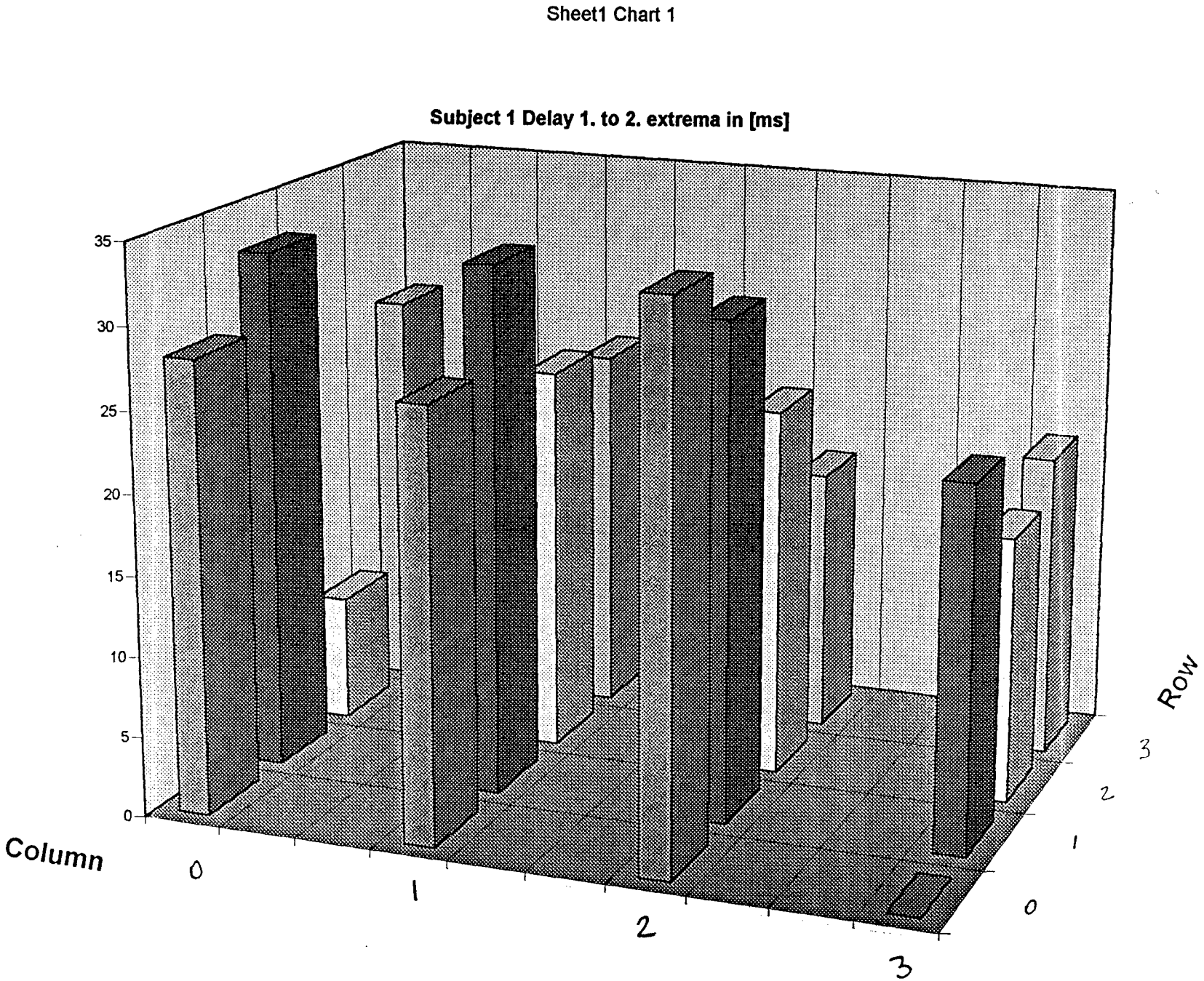

Sheet1 Chart 15
Subject V: Delays to second extrema in [ms]
ms
50
40
30
20
10
0
-10
Column
0
1
2
3
Row
0
1
2
3

FIGURE 7E

FIGURE 8A


Sheet1 Chart 1
Subject 1 Delay 1. to 2. extrema in [ms]
35
30
25
20
15
10
5
0
Column
0
1
2
3
Row
0
1
2
3

32

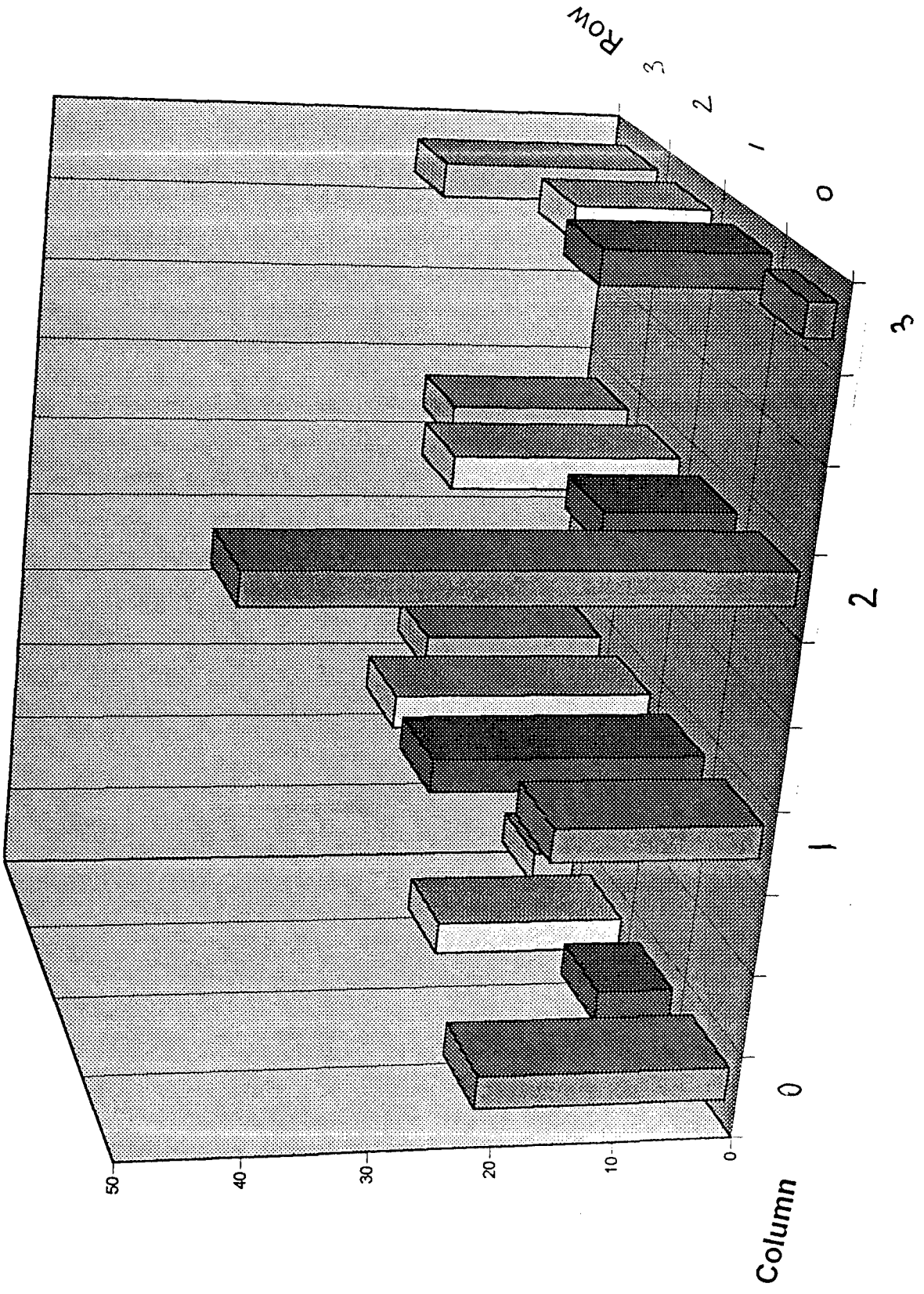

Sheet1 Chart 2
Subject II: Delays from 1. to 2. extremum
Row
0
1
2
3
Column
0
1
2
3
0
10
20
30
40
50

FIGURE 8B

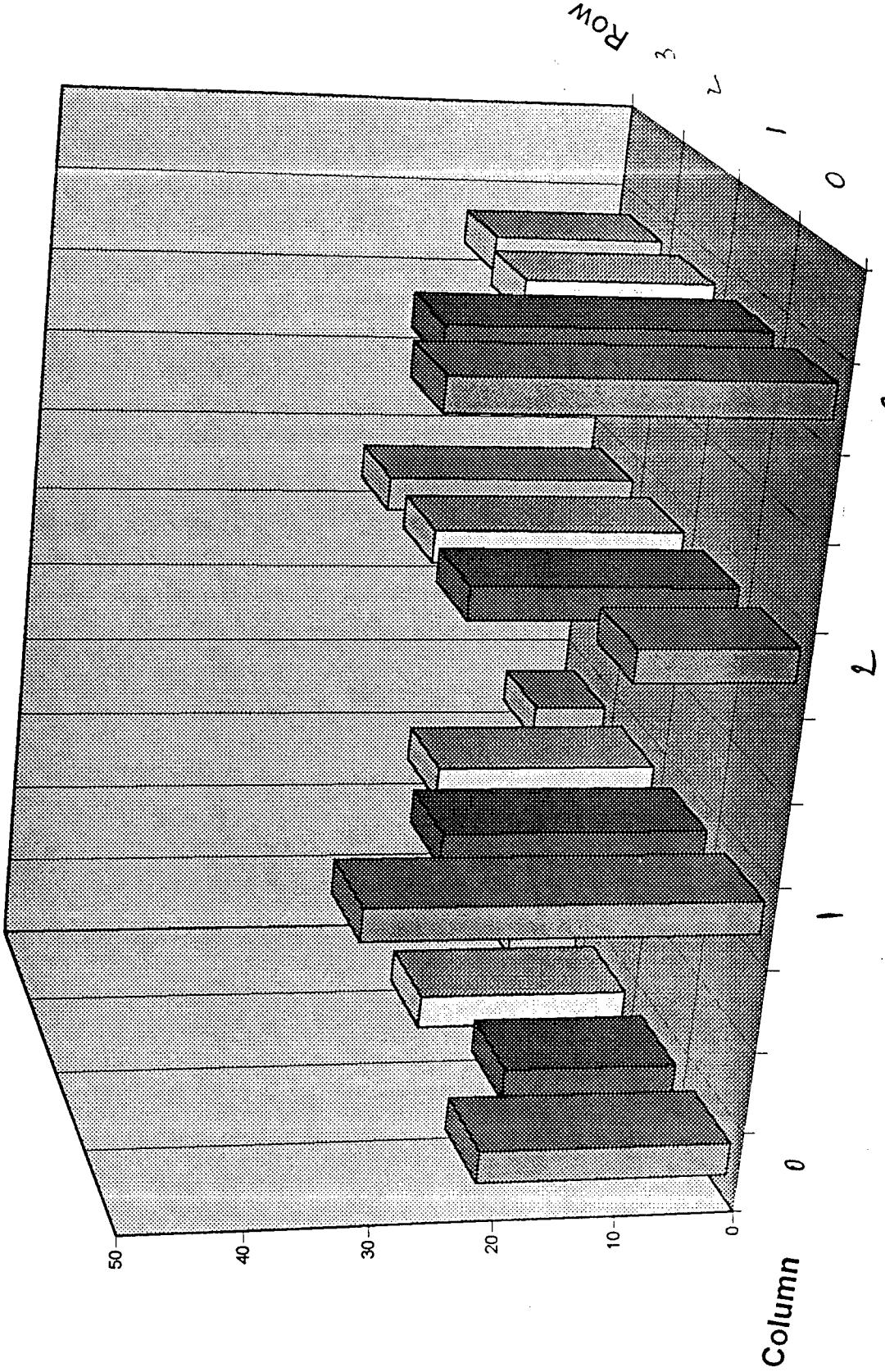

Sheet1 Chart 3
Subject III: Delay 1. to 2. extrema
Row
0
1
2
3
Column
0
1
2
3
0
10
20
30
40
50

FIGURE 8C

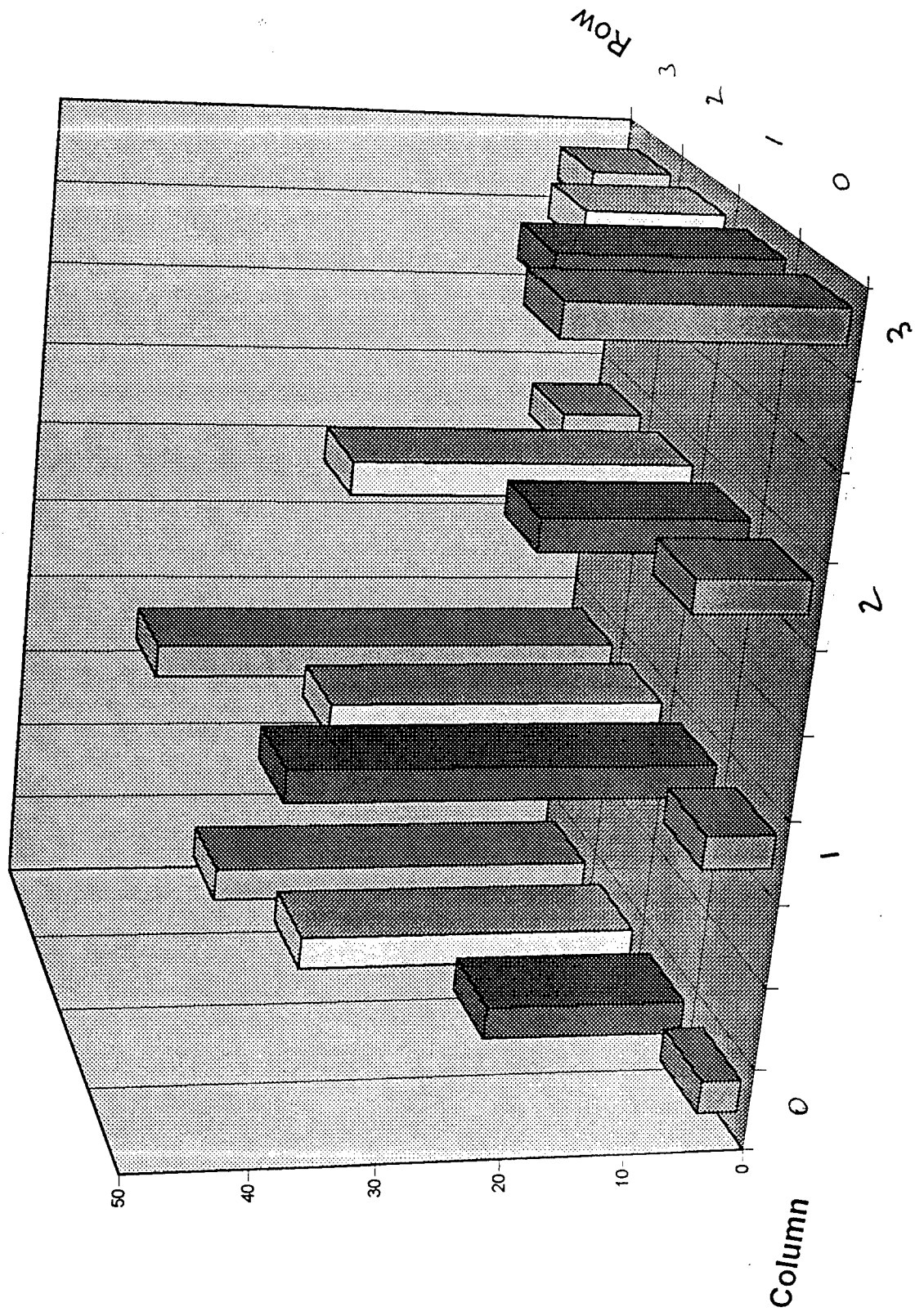

Sheet1 Chart 4
Subject IV: Delay 1. to 2. extremum
Row
Column
0
1
2
3
0
10
20
30
40
50

FIGURE 8D

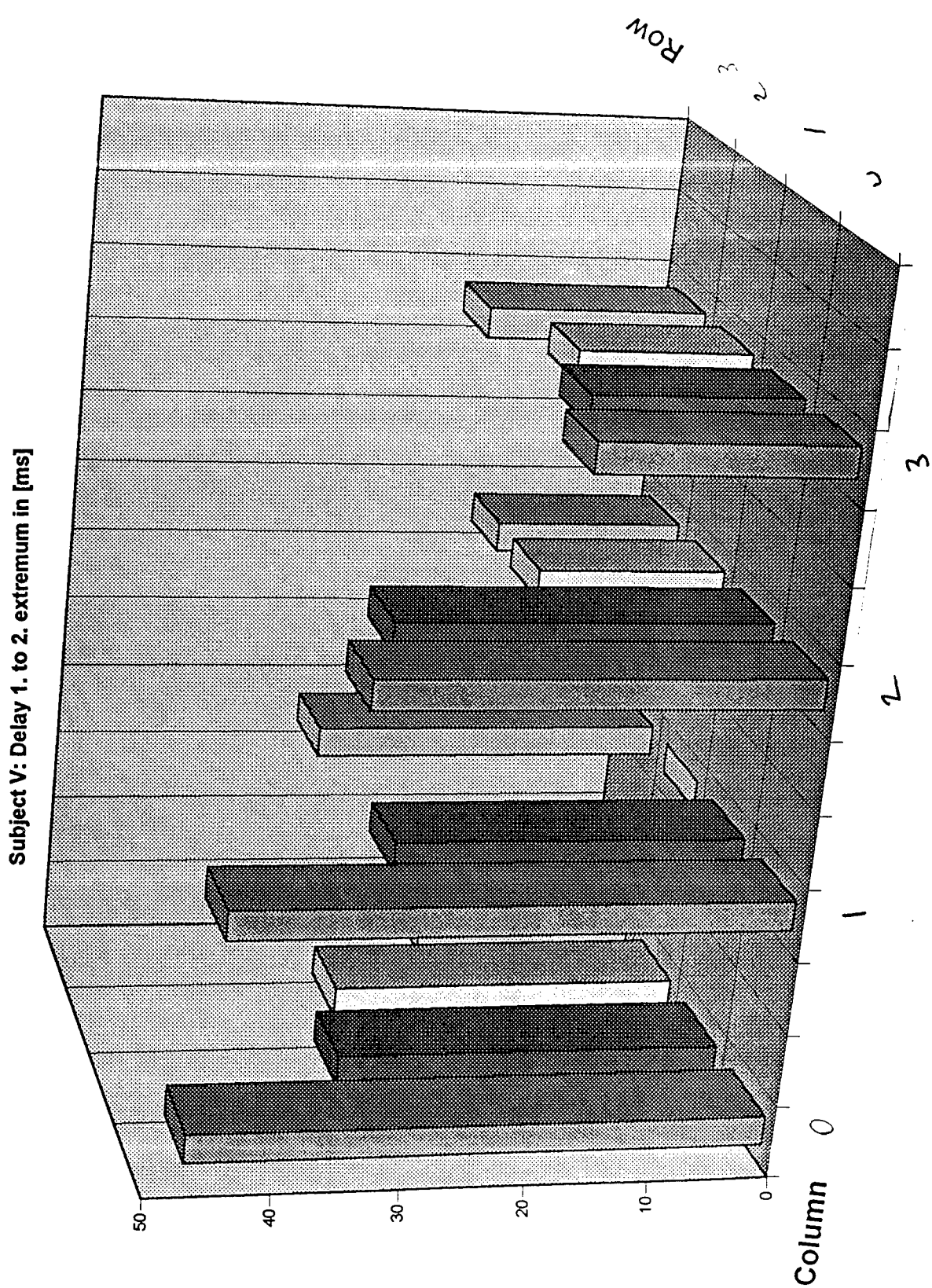

Sheet1 Chart 5
Subject V: Delay 1. to 2. extremum in [ms]
Row
Column
0
10
20
30
40
50
1
2
3

FIGURE 8E

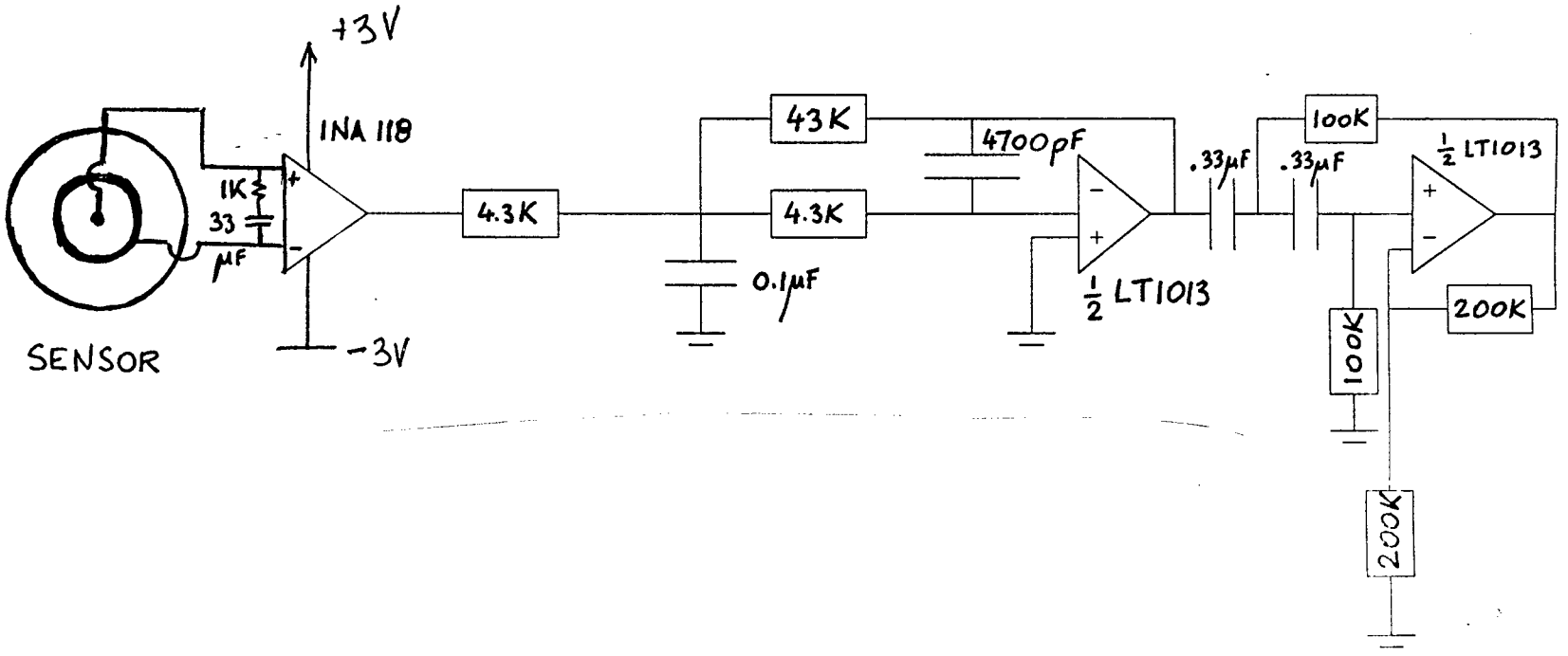


Figure 9. Circuit diagram inclusive of the low power amplifier and filter.

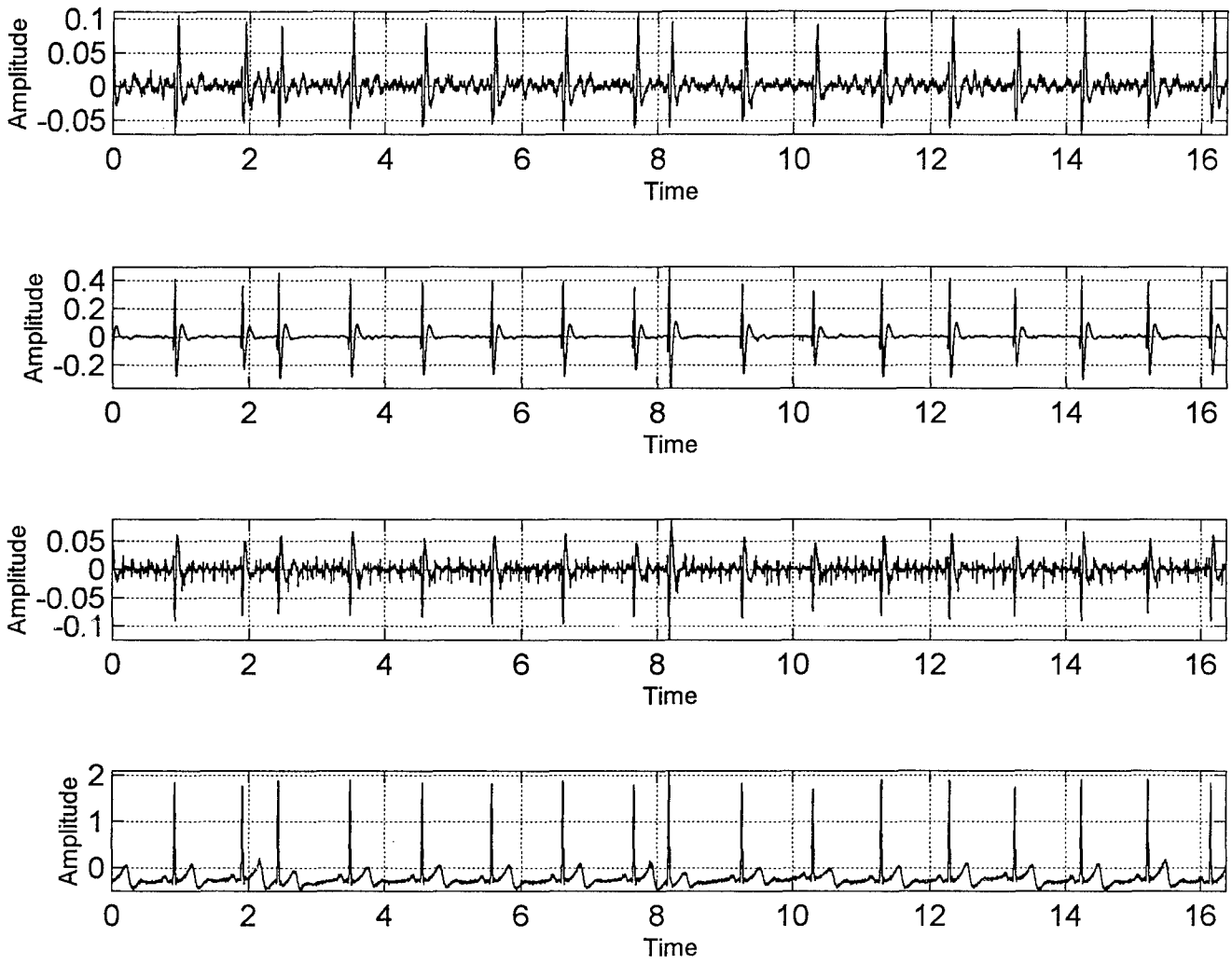
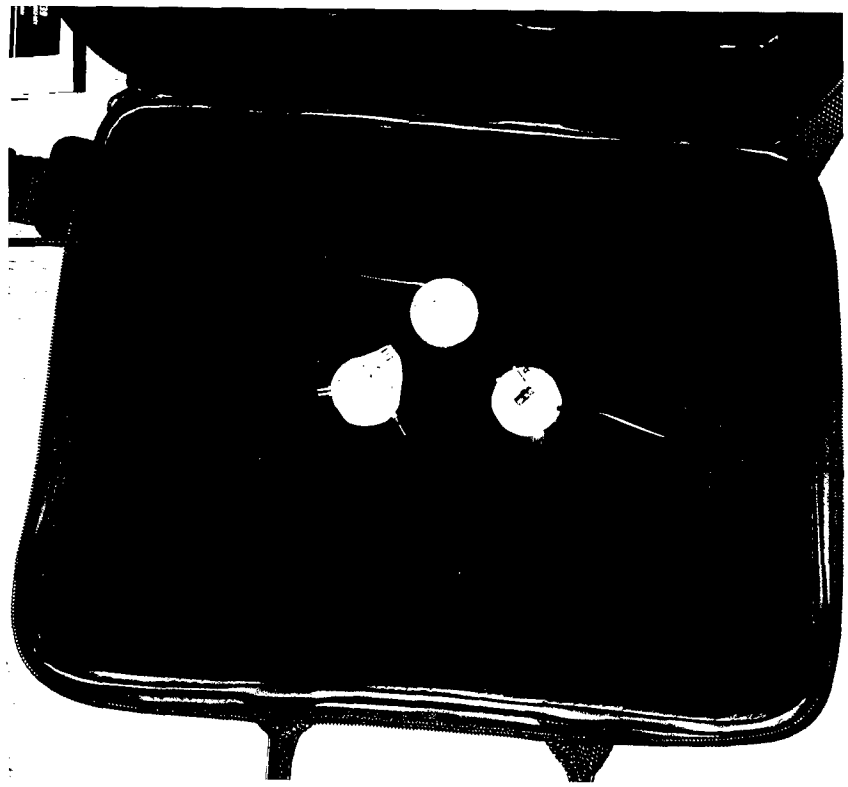
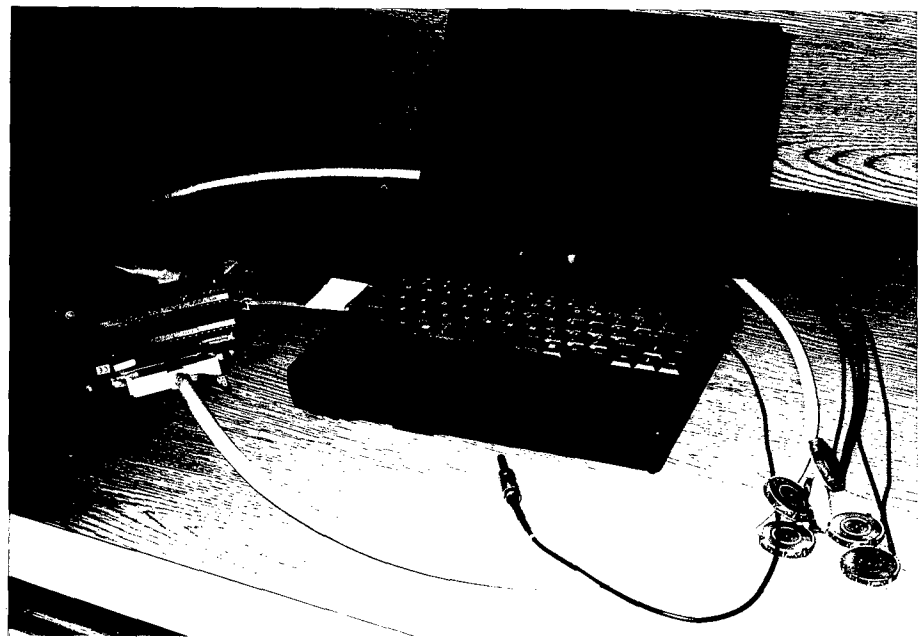


Figure 10. Four simultaneous channels from a subject who exhibited two premature atrial beats which resulted in ventricular electrograms typical of supraventricular beats (narrow QRS).

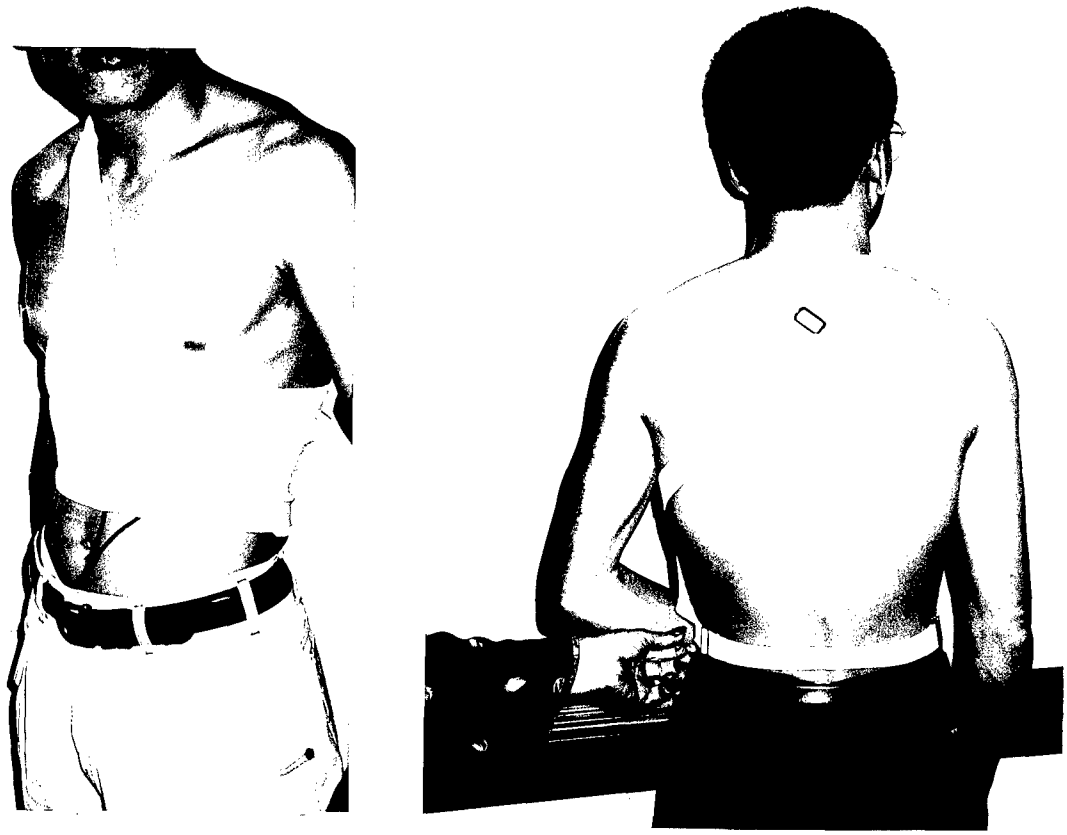


Photograph 1: Printed circuit boards showing electrodes, electronics and partially trimmed board.



Photograph 2: Lap-top computer used for data collection in battery powered mode, along with 5 completed sensor assemblies.

Photograph 3: Subject showing the locations of the three sensors which appear to be optimal for his anatomy from the viewpoint of signal amplitude, stability and signal to noise ratio.



Photograph 4: A male subject wearing the prototype harness with two sensors in place.

Photograph 6: The attachment of the harness on the subject's back.

Photograph 5: Another male subject wearing the prototype harness with two sensors in place, showing freedom of shoulder movement.

DEPARTMENT OF THE ARMY
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REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y) 4 Dec 02

MEMORANDUM FOR Administrator, Defense Technical Information Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

FOR THE COMMANDER:

Encl

PHYLIS M. RINEHART
Deputy Chief of Staff for
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